DEXAMETHASONE AS ADJUVANT TREATMENT IN PATIENTS WITH ACUTE SEVERE PHARYNGITIS: A DESCRIPTIVE STUDY AT WELCARE HOSPITAL EMERGENCY UNIT, DUBAI, UNITED ARAB EMIRATES

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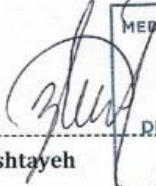
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Declaration

I, **Dr Bilal Ishtayeh** the undersigned, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree. I also declare that ethical approval for the study was obtained from the Health Research Ethics Committee of Stellenbosch University (Reference number: S11 /11 / 041).

Signed:-----------------------

Dr Bilal Ishtayeh

MEDICLINIC WELCARE HOSPITAL

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ABSTRACT

Background: An increased incidence of acute group A ß-hemolytic Streptococcal (GABHS) pharyngitis has been reported anecdotally at the Welcare Hospital in Dubai.

Aim: To describe the outcomes of patients with acute GABHS pharyngitis who received standard therapy at the Welcare hospital emergency unit in Dubai.

Objectives

To determine the time elapsed before patients experience a clinically significant reduction in pain.

To describe the side-effect profile of standard treatment received for acute GABHS pharyngitis.

Methods: This is a cross-sectional study design. Consecutive sampling of 123 patients was done from December, 2013 to March, 2014. A questionnaire was used to record demographic data and severity of GABHS before patients received standard treatment. The Visual Analogue Scale (VAS) was used to measure pain severity at baseline and during follow-up. Adults diagnosed with GABHS pharyngitis who received dexamethasone as part of standard treatment offered were included.

Results: Clinical pain relief, which was suggested as a VAS score of 4, was achieved by 5.7% of the patients at 12 hours. At 24 hours, 55.3% of the patients reported a VAS score of 4. The mean VAS score of the patients at this time was 4.12. A total of 99.2% of the patients reported a VAS score of 4 or lower at 36 and 48 hours. Paired t-test revealed statistically significant difference between the VAS scores at 12, 24, 36 and 48 hours and baseline (p=0.000). This suggests that clinical pain relief was achieved by 55.3% of the patients at 24 hours. At 48 hours, 21.1% of the patients reported a VAS score of 0. None of the patients reported any side effects associated with the one dose use of dexamethasone.

Conclusion: The findings suggest that dexamethasone is safe and effective to use as adjuvant for management of pain associated with acute GABHS pharyngitis. Almost all patients experienced significant pain relief by 36 and 48 hours and no side-effects related to dexamethasone use were recorded. Further definitive randomised controlled trials are needed to establish these findings as evidence for practice.

I. INTRODUCTION

Sore throat is among the commonest upper respiratory disorders reported in 2004 in Dubai with about 21, 244 cases of upper respiratory tract infections treated at primary health care centers the same year. (1) Upper respiratory tract infection rank among the top three most common diseases in the region with acute pharyngitis making up to 40% of this type of infection. (1,2) In the year 2004, there were 9, 746 cases of acute pharyngitis. (1)

Sore throat or acute pharyngitis is a common condition and is caused by bacterial or viral infections. (2) The most common bacteria causing acute pharyngitis are the group A ß-hemolytic Streptococci (GABHS) e.g. *Streptococcus pyogenes.* (2) Symptoms and signs such as pain, fever, absence of cough, anterior cervical lymph nodes and tonsillar exudates are used to diagnose acute GABHS pharyngitis. (2) The presence of three or all of these criteria have a positive predictive value of 40 to 60%, while absence of three or four of the criteria have a negative predictive value of 80%. (3) When these criteria are implemented in actual settings, the specificity and sensitivity of both measures are approximately 75%. (3)

The symptom of pain is generated when the pharynx and the lymphatic tissues that surround the pharynx become inflamed. (4) To reduce the pain, antibiotic treatment is given for bacterial infection, shortening the duration of the symptoms by as much as 2.7 days. (4) However, pain relief from antibiotic treatment is only moderate. The indiscriminate use of antibiotics is also discouraged in order to reduce the incidence of antibiotic resistance. (2) Supportive treatments such as oral analgesic, antipyretics or gargling of warm liquids may offer temporary pain relief. (4) In some patients suffering from severe pain, intramuscular (IM) or oral steroids are considered since these have been suggested to reduce inflammation and swelling faster than oral antibiotics. (4) Furthermore, randomised controlled trials (RCTs) suggested that patients suffering severe pain due to acute GABHS pharyngitis reported earlier pain relief with steroid therapy. (5,6,7,8)

Considering that increasing numbers of patients are suffering from respiratory infections in Dubai, there is a need to provide quality health care to these patients to ensure that they are adequately relieved of their symptoms during treatment.

However, there remains a paucity of studies describing the onset of pain relief following IMI or oral 10 mg dexamethasone in the current clinical research literature. In addition studies documenting the side effects from this kind of therapy have also not been reported. This study seeks to describe how patients presenting with symptoms of confirmed GABHS acute pharyngitis to Welcare Hospital would respond to the standard treatment regimen of acute pharyngitis, which include the use of dexamethasone.

II. LITERATURE REVIEW

Dexamethasone is a corticosteroid that is used to relieve inflammation in patients. (9, 10) The drug has many uses, which include relief of symptoms of pain in patients suffering from acute exudative pharyngitis. (10) The use of oral or intramuscular dexamethasone is shown to be effective in reducing pain levels in patients suffering from acute pharyngitis. (5) Onset of pain relief for patients receiving dexamethasone was 4 hours earlier as compared to those who were not administered with the corticosteroid. (5) Intramuscular injection of dexamethasone reduced pain levels faster than oral dexamethasone.(5) Wei et al. (5) further suggested that identification of the pathogen causing the acute pharyngitis would also play a role in the response of the patients to dexamethasone.

The study of Wei et al. (5) had a relatively large sample size (n=118) and the use of a double-blind controlled trial design minimised researcher bias. (9) Determining the effectiveness of an intervention requires quality randomised controlled trials as this type of study design provides robust results as compared to other study designs. The use of a control group serves as a basis for comparison of effects from a treatment group. (11) Furthermore, the effect size of the treatment could be determined when there is a larger sample size and patients are randomised to treatments. (12) However, the study did not provide data on numbers needed to treat (NNT).

A similar study among children ages 5 to 16 years old, however, showed a different result. Bulloch et al. (6) conducted a prospective, randomised, double blind, placebo-controlled trial among 184 children with acute pharyngitis in an emergency department. A rapid streptococcal antigen detection test was used to group the children. A total of 85 children tested positive while 99 children tested negative. Results showed that for children with group A beta-hemolytic streptococcal pharyngitis, the median time to experience relief from pain was 6 hours after oral dexamethasone. In the placebo group,

the median hours for clinically significant pain relief were 11.5 hours. Complete pain relief in both subgroups was however, similar at 36 hours. In the antigen-negative group, the median hours for clinical significant pain relief in the dexamethasone group were 13 hours while in the placebo group, the median hours for pain relief was 9 hours. Complete pain relief was similar at approximately 48 hours, which suggests that oral dexamethasone did not reduce the time to achieve clinically significant pain relief. However, for children with GABHS acute pharyngitis, oral dexamethasone did reduce the time of onset of clinically significant pain relief when compared to the placebo group. A review of the study also shows that it was robust and of high quality as researchers and patients were both blinded to the treatments offered. This would lessen researcher bias during interpretation of results. (10, 12)

Apart from the two RCTs mentioned above, two systematic reviews (7, 8) evaluated the effectiveness of steroids or corticosteroid in the treatment of acute GABHS pharyngitis. In the study by Wing et al. (7), corticosteroid treatment was examined for its effectiveness in relieving pain associated with acute GABHS pharyngitis. Findings revealed that when compared to placebo, corticosteroids provided a clinically meaningful 4.5 times reduction in pain relief. However, when follow-up was done at 24 hours, pain reduction using the visual analogue scale was not significantly different when compared to the placebo group. An important aspect of this systematic review was the determination of short-term side effects of the corticosteroids when compared to the placebo group. Analysis revealed that side effects were similar in both groups. However Wing et al. (7) suggested that treatment should be individualised and the use of corticosteroids not administered as routine treatment. This suggestion might have resulted from the observation that the use of corticosteroids provided pain relief during the period immediately after administration. Pain reduction, however, was similar to the placebo group 24 hours after corticosteroids were administered.

In another systematic review, (8) steroids were used as adjuvant therapy for patients suffering from acute pharyngitis. Findings suggested that dexamethasone provided pain relief 5.5 hours earlier when compared to other steroids such as prednisone or betamethasone. Findings of the review suggested that when a 10 mg IMI of dexamethasone was used as adjuvant to standard therapy, it led to rapid onset of pain relief for adults. In children, 10 mg of oral dexamethasone provided pain relief.

Systematic reviews (10) have been increasingly conducted in recent years to gather evidence on current medications or interventions for certain conditions. Quality systematic reviews allow health care practitioners to investigate whether an intervention is effective or not. The abovementioned two systematic reviews included only randomised controlled studies in their reviews. These studies suggest the effectiveness of dexamethasone as adjuvant treatment in relieving pain in patients receiving standard therapy for acute pharyngitis.

One gap seen in the studies reviewed (13, 14, 1,5, 16, 17, 18) is the lack of documentation of side effects of one dose of dexamethasone. It would appear that the focus of these studies was only in determining the effectiveness of dexamethasone in relieving pain. Today, the practise of administering oral or intramuscular dexamethasone as adjuvant therapy for acute GABHS pharyngitis varies widely. (18) In the UK, the NICE guideline (19), has not yet recommended the use of oral or IM dexamethasone in treating acute GABHS pharyngitis. The guideline is focused on delaying or withholding antibiotic treatment to prevent the side effects associated with constant use of antibiotics. However, it is suggested that oral or IM dexamethasone could provide pain relief in the absence of antibiotics. (9)

III. AIM AND OBJECTIVES:

The **aim** of this study was to assess pain relief in the first 48 hours among patients with acute GABHS pharyngitis who received standard therapy at the Welcare hospital emergency unit, Dubai.

The **objectives** of this study were as follows:
1. Determine the number of hours elapsed before patients experience clinically significant reduction in pain.
2. Describe the side-effect profile of standard treatment received for acute GABHS pharyngitis

IV. METHODS
4.1 Setting:
This study was conducted in the emergency unit of the Welcare Hospital in Dubai. This unit receives 6000 to 7000 patients each month. Approximately 1500-2000 of these patients suffers from upper respiratory tract infections (URTI). A third of those with

URTI are diagnosed with acute pharyngitis. Dubai's Welcare Hospital Emergency Unit currently has a standard treatment protocol for acute GABHS pharyngitis, which includes the administration of antibiotics (if patient is positive for GABHS) and the administration of intramuscular injection (IMI) or oral administration of 10 mg dexamethasone.

4.2 Study Design:

A descriptive cross sectional study design was utilised.

4.3 Sample Selection Strategy:

Patients were recruited through consecutive sampling. Inclusion criteria included the following: only adult patients who are at least 18 years old; who had no other health conditions except acute pharyngitis; who received usual care, which included the once off administration of dexamethasone as part of pain management; and who were residents of Dubai. All patients included had a rapid streptococcal antigen detection test performed.

4.4 Sample Size:

The study was descriptive and with the assistance of a statistician it was decided that all consecutive patients attending the emergency unit for treatment of acute GABHS pharyngitis over a period of three months were recruited for the study. The final sample size was dependent on the availability of patients who met the inclusion criteria at the time of study. This provided baseline information on the effects of dexamethasone in reducing pain in patients presenting with symptoms of acute GABHS pharyngitis. While consecutive sampling might not be representative of the whole population of patients in Dubai diagnosed with acute GABHS, the sample population would provide information on how patients receiving dexamethasone respond to this adjuvant treatment.

4.5 Instrument:

A checklist to obtain basic demographic data, the presence and severity of acute pharyngitis was used. In addition, the Visual Analogue Scale (VAS) (Appendix A) was used to measure the severity of pain of the patients at baseline and regular intervals after receiving standard usual treatment offered for acute GABHS pharyngitis. The scale

runs from zero to ten where zero represents no pain and ten the worst pain the patient could experience.

Pain perception is known to be difficult to measure (20) but the validity of the VAS tool in assessing pain is well established.(20,21) Three areas of validity such as criterion validity, content and construct validity have been established. Content validity would refer to the extent to which the tool can measure pain and nothing else. (21) Construct validity, on the other hand, would refer to the extent to which the measuring tool is consistent with other tools in measuring pain. (21) Finally, criterion validity would require that the measuring tool could predict an observable phenomenon. (20,21) The sensitivity and specificity of VAS have also been established. A number of studies (13, 14, 15, 16, 17, 18) have established the specificity and validity of these tools in measuring pain.

4.6. Data collection:

Once patients had signed informed consent to participate in the study, measurement of pain was done with the use of the Visual Analogue Scale (VAS). A score of "10" indicated maximum pain experienced and a score of "0" indicated no pain. The patients' level of pain relief was recorded at baseline and at 12, 24, 36 and 48 hours follow up. The researcher and field workers followed-up the patients by telephone. The participants were also asked to report any side effects related to use of dexamethasone such as headache, increased sweating, dizziness, nausea or stomach pain, muscle weakness and sleep problems after standard treatment was administered. (13, 14) Patients would have received 10 mg of dexamethasone intramuscularly as part of their usual standard care at Dubai hospital emergency centre.

4.7 Ethical Considerations:

The researcher explained the aims and objectives of the study to each patient who was administered with dexamethasone. Once the patient consented to be followed-up in the next 48 hours, the patient was asked to sign informed consent. Participants were also assured that their identities were protected and they would remain anonymous throughout the study. Once data became available, electronic data were password protected while hard copies were kept in locked file cabinets. The Institutional Review Board and the Ethics Department of the University of Stellenbosch approved the study. Password protected data would be kept for future reference at the completion of the

study. Findings will be disseminated at the Welcare Hospital and other academic research forum.

4.7 Data analysis

Statistical Package for Social Sciences (SPSS) was used to analyse data. The mean score at the onset of clinical pain relief was recorded. This was done by subtracting the VAS score at baseline from the VAS score at 12, 24, 36 and 48 hours follow-up. The researcher conducted the follow-up through telephonic discussion with the patient. The participants were asked to report any side effects experienced after treatment had been administered. The Dependent t-test for paired samples was used to detect significant changes of mean VAS pain scores from baseline to 12, 24, 36 and 48 hours follow-up. Side-effects were not statistically treated since none of the participants reported any side-effects during follow-up.

V. RESULTS

A total of 123 patients were consecutively sampled during this period. More females (n=68) were recruited than males (n=55). The mean age of the patients was 31.3 ± 9.6 years. Almost a third, 29.3% (n=36) of the patients were positive in the rapid streptococcal antigen test while 70.7% (n=87) reported negative for the test. Majority of participants, 62.6% (n=77) consented to receive antibiotics while 37.4% did not receive antibiotics (n=46).

Baseline: Visual Analogue scores for throat pain at baseline is shown in table 1. The VAS score at this time ranged from 6 to 10 with a mean score of 8.3. The vast majority of participants (74.8%) scored their pain 8 to 9.

Table 1. Patients' visual analogue scale (VAS) score at baseline

		Frequency	Percent	Cumulative Percent
Valid	6	6	4.9	4.9
	7	11	8.9	13.8
	8	57	46.3	60.2
	9	35	28.5	88.6
	10	14	11.4	100.0
	Total	123	100.0	

12 hours after baseline: Patient VAS scores after 12 hours ranged from 4-8. Only 5.7% (7) reported a pain score of 4 after 12 hours following the administration of dexamethasone. Results also showed that the mean VAS score had decreased to 6.11 from a mean VAS score of 8.3 at baseline. More than 52% (64) reported a pain score of 6. Table 2 presents the frequency of patients with VAS scores of 4 to 8:

Table 2. Patients' visual analogue scale (VAS) scores after 12 hours

		Frequency	Percent	Cumulative Percent
Valid	4	7	5.7	5.7
	5	19	15.4	21.1
	6	64	52.0	73.2
	7	20	16.3	89.4
	8	13	10.6	100.0
	Total	123	100.0	

After 24 hours: The mean VAS score of the patients was 4.12. VAS scores ranged from 1 to 7. More than half 55.3% (68) of the patients reported a VAS score of 4. Results reveal that majority of the patients experienced clinical relief at 24 hours as shown in table 3.

Table 3. Patients' visual analogue scale (VAS) scores after 24 hours

		Frequency	Percent	Cumulative Percent
Valid	1	1	.8	.8
	2	14	11.4	12.2
	3	5	4.1	16.3
	4	68	55.3	71.5
	5	21	17.1	88.6
	6	12	9.8	98.4
	7	2	1.6	100.0
	Total	123	100.0	

36 hours after: Mean VAS scores of the patients at 36 hours was 2.16. Almost 70% of the patients reported a pain score of 2 as shown in table 4:

Table 4. Patients' visual analogue scale (VAS) scores after 36 hours

		Frequency	Percent	Cumulative Percent
Valid	1	17	13.8	13.8
	2	83	67.5	81.3
	3	12	9.8	91.1

4	8	6.5	97.6
5	3	2.4	100.0
Total	123	100.0	

After 48 hours: The mean VAS scores was only 1.24. Twenty-six of the patients reported a pain score of 0 and only 1 patient reported a pain score of 5. The majority or 75.6% either reported a pain score of 1 or 2 as reflected in table 5.

Table 5. Patients' visual analogue scale (VAS) scores after 48 hours

		Frequency	Percent	Cumulative Percent
Valid	0	26	21.1	21.1
	1	51	41.5	62.6
	2	42	34.1	96.7
	4	3	2.4	99.2
	5	1	.8	100.0
	Total	123	100.0	

Clinical pain relief was determined by subtracting the VAS scores at 12, 24, 6 and 48 hours from the baseline VAS scores. The table 6 below presents the Mean VAS scores at baseline, 12, 24, 36 and 48 hours and clinical pain relief:

Table 6. Clinical Pain Relief

Time	Mean Vas Scores	Clinical Pain Relief (baseline- VAS score)
Baseline	8.33	
12 hours	6.11	8.33-6.11= **2.22**
24 hours	4.12	8.33-4.12= **4.21**
36 hours	2.16	8.33-2.16= **6.17**
48 hours	1.24	8.33-1.24= **7.09**

As presented in the table above, clinical pain relief at 12 hours was 2.22 and 4.21 at 24 hours. This increased to 6.17 at 36 hours and 7.09 at 48 hours.

Results of the paired sample t-test revealed a statistically significant difference (p=0.000) between the means of the VAS scores at baseline and at 12 hours. The same results are also seen between the means of the VAS scores at baseline and at 24 hours (p=0.000). Statistically significant differences in the mean scores at baseline and at 36 and 48 hours were also observed (p=0.000).

Side-effects: None of the patients reported any adverse effects associated with dexamethasone during the 48-hour period of follow up.

VI. DISCUSSION

Pain management is essential to promote positive health outcomes amongst patients. (21) Physiological effects of unmanaged pain include increased heart rate, a compromised immune system and increased risk of stress and depression. (21) All these could delay recovery of patients suffering from pain related to a health condition. Results of this study show that administration of dexamethasone resulted in a reduction of pain scores as shown by the visual analogue scale. While there were statistically significant differences between the mean scores at baseline and during the follow-ups at 12, 24, 36 and 48 hours, clinical pain relief shown by a score of 4 or less was achieved at 24 hours in the majority of patients. Miller (22) suggests that a VAS score of 4 is considered as a critical threshold in determining whether patients have benefitted from a therapy.

Miller (22) explains that patients who report a VAS score of 4 tends to show improvements compared to patients who report pain scores higher than 4. Results show that patients report a mean score of 4.12 at 24 hours. This suggests that pain severity reduced significantly with time elapsed from baseline. However, findings also show that at 12 hours, only 5.7% of the patients reported a VAS score of 4. At 24 hours, more than half or 55% of the patients already reported a pain score of 4. Almost all (97.6%) of the patients reported a VAS score of 4 and lower at 36 hours. This shows that almost all of the patients clinically benefitted from dexamethasone at 36 hours. At 48 hours, 99.2% of the patients reported a VAS score of 4 and lower. Importantly, 21.1% of the patients reported a VAS score of 0 or complete pain relief at 48 hours.

Since this study is descriptive, it was impossible to determine if similar findings are observed when patients receive only antibiotics to manage acute GABHS pharyngitis. An earlier study (4) suggests that pain relief from GABHS pharyngitis following antibiotic medication is achieved at 2.7 days using VAS tool. However, investigators of this study failed to report the proportion of patients who reported a VAS score of 4 during the follow-up period. This could have provided information on whether clinical pain relief was achieved earlier. When compared to the findings of the present study, mean VAS score of 4 was achieved at 24 hours. At this time, more than half of the patients already

reported pain scores of 4, which has been suggested to lead to improvements in health outcomes. (22) At 48 hours, almost all of the patients already reported a VAS score of 4 or lower, suggesting that clinical pain relief is achieved at 48 hours. (4)

The findings of the present study are also supported by that of Wei et al. (5) who showed that clinical pain relief was achieved 4 hours earlier with IM dexamethasone compared to placebo only. This suggests that use of dexamethasone in pain management is feasible since earlier pain relief is achieved. Results of this study show that pain relief is attained within the first 24 hours of administration of the drug. Although comparisons were not made between patients who received dexamethasone and those who only received antibiotics or supportive treatment, results of the present study suggests that dexamethasone could be used for pain management.

In the present study, none of the patients reported any side effects associated with steroid use during the follow-up period. Concerns (6,7,8) have been raised on the possible side effects of dexamethasone. Side effects of dexamethasone are similar to other steroids, which could include cushingnoid effects. (23) However, these become more evident with prolonged use of steroids. (23) It is still unclear whether the risk of developing these side effects would be similar if a patient only receives the drug once as adjuvant therapy for pain management of acute pharyngitis.

Findings of this study also highlight the importance of comparing when clinical pain relief is achieved between patients who received only antibiotics against those who received dexamethasone at the Welcare Hospital in Dubai. This would show which type of treatment could lead to earlier clinical pain relief. Although only a small proportion (29%), of patients tested positive for GABHS, more than twice the number of patients was prescribed antibiotics. This suggests the need for further physician and patient education on the uses and side effects of antibiotics, particularly where patients have tested negative for the rapid streptococcal antigen detection test . The findings suggest that administration of dexamethasone as part of standard care could successfully manage pain in patients suffering from acute GABHS pharyngitis. Furthermore, none of the patients who consented to be followed-up reported any side effects associated with dexamethasone.

VII: LIMITATIONS OF STUDY

Findings should be taken with caution since this study was descriptive and did not recruit patients randomly. The investigator only recorded when clinical pain relief is achieved following the use of dexamethasone. It is unclear if dexamethasone contributed to this pain relief since this study did not use a control group to compare findings. Another limitation of this study includes lack of comparison of VAS scores of patients who received dexamethasone against those who received antibiotics or supportive treatment only. Findings are only limited to the sampled population and could not be generalised to a larger and more heterogeneous population. Despite these limitations, the study suggests that the one dose of dexamethasone could be a safe alternative in pain management of patients with acute pharyngitis. It is also noteworthy that perception of pain is highly variable (24) with some having higher tolerance for pain while the rest may show a higher sensitivity to pain. Hence, the use of mean scores in the visual analogue scale might not truly reflect individual patient's experience of clinical pain relief. Although a VAS score of 4 (22) has been reported to lead to better health outcomes and improvements, it is possible that even if patients report a pain score of 4, they might not experience better health outcomes.

Despite the lack of generalisability, other health care settings might replicate similar findings upon administration of dexamethasone to manage pain in patients with acute GABHS pharyngitis. Importantly, the absence of reported side effects might be encouraging since a major concern regarding the use of dexamethasone is related to its reported side effects. Finally, it is recommended that a randomized controlled trial (RCT of dexamethasone versus placebo, sub-analyzed by antibiotic versus no antibiotic group should be conducted in order to establish the efficacy of dexamethasone.

VIII. CONCLUSION

The use of dexamethasone as adjuvant treatment in GABHS pharyngitis is safe and associated with rapid and clinically significant pain relief as early as within 24 hour after dexamethasone administration. In view of the limitations of this study, better- designed randomized controlled trials are needed to validate these findings.

IX. REFERENCES:

1. National Statistics Report 2004. Dubai: National Statistics Office; 2004.

2. Melio F & Holmes D. Upper respiratory tract infections. In: Rosen P, Barkin R editors. Emergency medicine: concepts and clinical practice. 4th edn. St. Louis, MO: Mosby; 1998; 529-1553.

3. Mintz M. Disorders of the respiratory tract: common challenges in primary care. New Jersey: Humana Press; 2006.

4. Shores C. Infections and disorders of the neck and upper airway. In: Tintinalli J, Kelen G, Stapczynski J, editors. Emergency medicine: a comprehensive study guide. 6th edn. New York: McGraw-Hill Co; 2004; 1494-1501.

5. Wei J, Kasperbauer J, Weaver A, Boggust A. Efficacy of single-dose as adjuvant therapy for acute pharyngitis. Laryngoscope. 2002;112: 87 -93.

6. Bulloch B, Kabani A & Tenebein M. Oral dexamethasone for the treatment of pain in children with acute pharyngitis: a randomised, double-blind, placebo-controlled trial. Ann Fam Med. 2003; 41(5): 601-608.

7. Wing A, Villa-Roel C, Yeh B, et al. Effectiveness of corticosteroid treatment in acute pharyngitis: a systematic review of the literature. Acad Emerg Med. 2010: 17(5): 476-483.

8. Korb K, Scherer M, Jean-François, C. Steroids as adjuvant therapy for acute pharyngitis in ambulatory patients: a systematic review. Ann Fam Med. 2010: 8(1): 58-63.

9. Greenhalgh T. How to read a paper: the basics of evidence-based medicine. West Sussex, UK: John Wiley and Sons; 2010.

10. Cooper R, Hofman J, Barlet J, et al. Principles of appropriate antibiotic use for acute pharyngitis in adults. Ann Intern Med. 2001;134:509-517.

11. Hek G, Judd M, Moule P. Making sense of research (4th ed.). London: Sage Publications; 2011.

12. Solomon P, Cavanaugh M, Daine, J. Randomised controlled trials: design and implementation for community-based psychosocial interventions. Oxford: Oxford University Press; 2009.

13. Kiderman A, Yaphe, J, Bregman J, et al. Adjuvant prednisone therapy in pharyngitis: a randomised controlled trial for general practice. Br J Gen Pract. 2005; 55(512): 218-221.

14. Tesar A, Yanturali S, Topacoglu H, et al. Clinical efficacy of dexamethasone for acute exudative pharyngitis. J Emerg Med. 2008; 35(4): 363-367.

15. Marvez-Valis E, Ernst A, Gray, J, Johnson W. The role of betamethasone in the treatment of acute exudative pharyngitis. Acad Emerg Med. 1998; 5(6): 567-572.

16. Niland M, Bonsu B, Nuss K, Goodman D. A pilot study of 1 versus 3 days of dexamethasone as add-on therapy in children with streptococcal pharyngitis. Pediatr Infect Dis J. 2006; 25(6): 477-481. .

17. Olympia R, Khine H, Avner J. Effectiveness of oral dexamethasone in the treatment of moderate to severe pharyngitis in children. Arch Pediatr Adolesc Med. 2005; 159(3): 278-282.

18. Centor R, Allison J, Cohen S. Pharyngitis management: defining the controversy. J Gen Intern Med. 2007; 22(1): 127-130.

19. National Institute for Clinical Excellence (NICE). Respiratory tract infections-antibiotic prescribing. London: NICE; 2008.

20. Kaplan E, Gooch W, Notario G, Craft JC. Macrolide therapy of group A streptococcal pharyngitis: 10 days of macrolide therapy (Clarithromycin) is more effective in streptococcal eradication than 5 days (Azithromycin). Clin Infect Dis. 2001;32:1798-1802.

21. McMain, L. Principles of acute pain management. J Periop Pract. 2008;18:472-478.

22. Miller, G. Studying the difference between 'statistical' and 'clinically meaningful'. Pain Medicine News. 2010; 8(9).

23. Macintyre, P. & Schug, S. Acute pain management: A practical guide. Philadelphia, PA: Elsevier Limited; 2007.

24. Kelly, A. The minimum clinically significant difference in visual analogue scale pain score does not differ with severity of pain. Emerg Med J. 2001; 18(3): 205-207.

Appendix A. Visual Analogue Scale

Instruction:

The researcher will present the patient with the visual analogue score card below. The patient will be asked to point to a line between the faces to indicate how much pain they are currently feeling. A score of zero means 'no pain' while a 10 means 'the most severe pain'.

No Pain   Worst pain ever

0   1   2   3   4   5   6   7   8   9   10
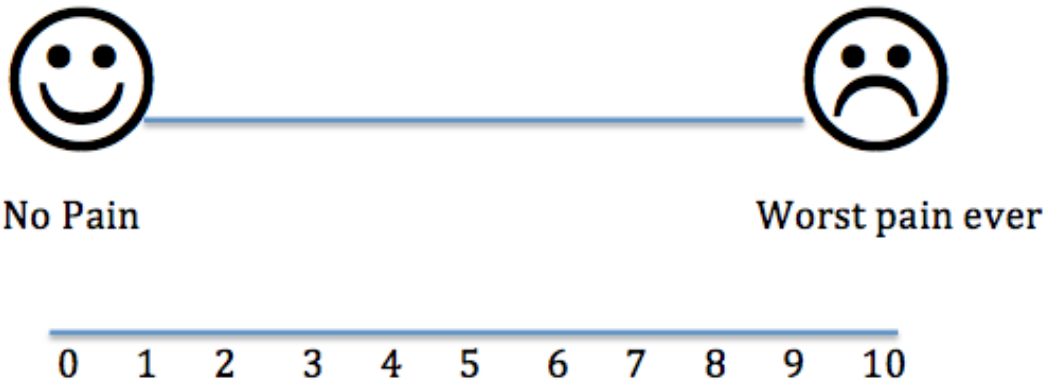
Appendix B. Declaration Page

A. RESEARCHER

Surname	ISHTAYEH, BILAL			Initials		Title	Doctor
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Department							
Present position	GP			E-mail	bishtayeh@yahoo.com		
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B. PROJECT TITLE (MAXIMUM OF 250 CHARACTERS FOR DATABASE PURPOSES)

Dexamethasone as adjuvant treatment in patients with acute severe pharyngitis in an emergency unit of a hospital in Dubai: A descriptive study

I, Dr. Bilal Ishtayeh declare that

- I have read through the submitted version of the research protocol and all supporting documents and am satisfied with their contents
- I am suitably qualified and experienced to perform and/or supervise the above research study.
- I agree to conduct or supervise the described study personally in accordance with the relevant, current protocol and will only change the protocol after approval by the HREC, except when urgently necessary to protect the safety, rights, or welfare of subjects. In such a case, I am aware that I should notify the HREC without delay.
- I agree to timeously report to the HREC serious adverse events that may occur in the course of the investigation.
- I agree to maintain adequate and accurate records and to make those records available for inspection by the appropriate authorised agents when and if necessary.
- I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in the Declaration of Helsinki, as well as South African and ICH GCP Guidelines and the Ethical Guidelines of the Department of Health as well as applicable regulations pertaining to health research.
- I agree to comply with all regulatory and monitoring requirements of the HREC.
- I agree that I am conversant with the above guidelines.
- I will ensure that every patient (or other involved persons, such as relatives), shall at all times be treated in a dignified manner and with respect.
- I will submit all required reports within the stipulated time frames.

Principal / Sub- / Co-investigator /Supervisor MEDICLINIC WELCARE BILAL ISHTAYEH

Signature

د. بلال أحمد اشتيه
طبيب ممارس عام
DR. BILAL AHMED ISHTAYEH
General Practitioner

Date February____, 2014

CONFLICT OF INTEREST DECLARATION (OBLIGATORY) /LS/2392011/243068

I, Bilal Ishtayeh declare that

☑ I have no financial or non-financial interests, which may inappropriately influence me in the conduct of this research study.

Appendix C. Informed Consent

Participant Info Sheet and Consent Form

Info Sheet:

Informed Consent Letter

Participant Identification Number _____

Title of Study :   *"Dexamethasone as adjuvant treatment in patients with acute severe pharyngitis in an emergency unit of a hospital in Dubai: A descriptive study."*

Name of Researcher: **Dr Bilal Ishtayeh**

I (name of key informant) have been consulted by Dr. Bilal Ishtayeh regarding my participation as a participant in his study. I was given the opportunity to ask Dr. Bilal Ishtayeh about the study and its aims and objectives. I understand what is involved in my participation and have given my consent.

I also understand that at any time of the data collection period, I can withdraw without having to give the researcher any reasons for doing so.

I also understand that any data collected during the study will be used for academic purposes only. I was also assured that my identity or participation in the study would never be revealed. If this study will be published or parts will be disseminated in any type of academic settings, I am giving my consent to these activities.

_____   _____   _____
Name of Key Informant   Date   Signature

MEDICLINIC WELCARE HOSPITAL
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طبيب ممارس عام
DR. BILAL AHMED ISHTAYEH
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