ISRCTN17435450 https://doi.org/10.1186/ISRCTN17435450

Treatment Options without Antibiotics for Sore Throat (TOAST)

Submission date
26/03/2013

Recruitment status
No longer recruiting

Registration date
26/03/2013

Overall study status
Completed

Last Edited
08/05/2017

Condition category
Respiratory

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Currently nearly half of all patients who come to see their GP with acute (sudden) sore throat are treated with antibiotics. However, national guidelines do not recommend antibiotics for the majority of patients, particularly because inappropriate use of antibiotics contributes to the development of antibiotic resistance. Corticosteroids are drugs which have been shown to work in other infections of the airways such as croup. Evidence suggests that using corticosteroids to treat sore throat improves symptoms when given in addition to antibiotics. This study is investigating whether corticosteroids given without antibiotics can ease the symptoms of a sore throat, and whether they are cost effective.

Who can participate?
Adults with a sore throat with symptoms starting within the last seven days.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given 10mg of dexamethasone (in pill form) Those in group 2 are given a placebo (dummy) pill. They take the medication at their initial GP appointment and are asked to complete a symptom diary every day for 7 days. They are also be asked at 24 and 48 hours via text message or telephone if their sore throat gets better. At one month their medical notes are reviewed by their GP to see what further treatment they receive during that time.

What are the possible benefits and risks of participating?
There are no guaranteed benefits from taking part in this study. However, participants will be helping research to improve the treatment of sore throats in the future. There are a number of risks to taking part. A participants sore throat may not improve after taking the trial medication. Even if they are randomly allocated the corticosteroid medication, it is not yet proven to be an effective treatment for sore throats by itself. There is a small risk of side effects from taking dexamethasone. A short course of corticosteroids usually causes no sideeffects. For example, a 1 2 week course is often prescribed to ease a severe attack of asthma and this is usually taken without any problems. Sideeffects are more likely to occur if it’s taken for longer than 23 months or if short courses of treatment are taken repeatedly. Rare side effects include having an allergic reaction to the dexamethasone, becoming confused with hallucinations or delusions,

or very low in mood. Common side effects which are unlikely to have any lasting consequences are dyspepsia or heartburn and difficulty getting to sleep. Finally, participants are being asked to make a commitment to complete a symptom diary which may take up to 5 minutes every day for 7 days; and receive text messages or telephone calls at 24 and 48 hours after treatment from the trial research team.

Where is the study run from?
Department of Primary Health Care (UK)

When is the study starting and how long is it expected to run for?
February 2013 to April 2015

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Johanna Maughan
johanna.maughan@phc.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Johanna Maughan

ORCID ID
http://orcid.org/0000-0002-8750-8995

Contact details
Department of Primary Health Care
23-38 Hythe Bridge Street
Oxford
United Kingdom
OX1 2ET
-
johanna.maughan@phc.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
2012-004330-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13667

Study information

Scientific Title
Do oral corticosteroids provide clinical and cost-effective symptom relief for sore throat? A multicentre, double blind, randomized, placebo-controlled trial

Acronym
TOAST

Study objectives
This trial is looking at different options for sore throat treatments. Currently nearly half of all acute sore throats presented in primary care are treated with antibiotics. However, this is an expensive option, is not proven to be effective in all situations and antibiotic resistance is on the rise. We are therefore looking at the use of a corticosteroid to treat acute sore throats. The trial will look at a steroid versus placebo in sore throat treatment and then also at two groups, one being those that are given antibiotics alongside the steroid treatment and the other those that are only given the steroid treatment. We are interested in seeing whether a steroid alone is effective in reducing sore throat symptoms in 24 and 48 hours and whether this approach is more cost effective in the long term. The participants will be randomised to receive either a placebo or steroid and neither they nor the doctor will know what treatment they are being given. The steroid being used is Dexamethasone, one 10mg dose will be given. This is a standard dose and safe for short term use. The trial will be run from three centres; Oxford, Bristol and Southampton and will run in GP surgeries in those regions. Eligible patients are those who are over 18 and whose sore throats meet various sore throat measuring criteria. Those people who are eligible will take one dose of medication, either placebo or steroid, and then will be asked to complete a symptom diary every day for the following 7 days. They will also be asked at 24 and 48 hours if their sore throat has resolved via text or phone. At one month their medical notes will be reviewed by their GP to see what further treatment they have received.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford B, 20/12/2012, ref: 12/SC/0684

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Sore throat

Interventions
Current interventions as of 21/07/2016:
Participants are randomly allocated to one of two groups:
Treatment arm: 10mg dexamethasone, over-encapsulated and given in one oral dose at the time of recruitment
Control arm: Lactose, over-encapsulated with an identical capsule and given in one oral dose at the time of recruitment

Previous interventions:
Dexamethasone/Placebo, one 10mg oral dose of dexamethasone on the day of presentation of their sore throat or a placebo

Follow Up Length: 1 month(s)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Dexamethasone

Primary outcome measure
Direct report by the patient of presence or absence of complete resolution of sore throat at 24 hours by either text message or telephone

Secondary outcome measures
1. Direct report by those patients who have not been prescribed antibiotics of presence or absence of complete resolution of sore throat at 24 hours by either text message or telephone
2. Report of presence or absence of complete resolution of sore throat at 48 hours by either text message or telephone contact
3. Report of time to onset of pain relief (in hours) within 7 days
4. Report of time to complete symptom resolution (in hours) within 7 days
5. Report of difficulty swallowing and pain on swallowing over the 7 days from treatment onset
6. Duration of moderately bad symptoms recorded by validated symptom diary over the 7 days from treatment onset
7. Severity of symptoms in the 2-4 days after seeing the doctor based on the symptom diary
8. Change in ratings of sore throat pain and pain on swallowing by visual analogue scale
9. Uptake of delayed antibiotic prescription within 7 days
10. Time missed from work or education over subsequent 7 days
11. Attendance at GP practice, A and E or Out of hours (OOH) centres within 28 days with symptoms or complications associated with sore throat e.g. peritonsillar abscess
12. Hospital admission with related complications of sore throat within 28 days
13. Use of over-the counter medications and prescription medications (including whether, if

delayed antibiotics are taken, the course is completed, and whether any other antibiotics were taken) in the first 7 days
14. Cost effectiveness measures: Euroqol 5D score change in 7 days and impact on usual activities over 7 days

Overall study start date
01/02/2013

Completion date
16/04/2015

Eligibility

Key inclusion criteria
1. Male and female aged 18 years or above
2. Presenting to a primary care appointment with acute sore throat and odynophagia (pain on swallowing) which is judged by the clinician to be infective in origin
3. Onset of symptoms within the last 7 days
4. Patient has capacity and willingness, in the view of the recruiting clinician, to give consent and complete the trial paperwork, including the Symptom Diary

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 510; UK Sample Size: 510

Key exclusion criteria
1. Female participant who is pregnant, lactating or planning pregnancy during the course of the study
2. Recent (<1 month) use of inhaled or oral corticosteroids
3. Recent (<1 month) Adenotonsillectomy
4. Currently or recently (<14 days) taking antibiotics
5. Clear alternative diagnosis e.g. Pneumonia
6. Known immune-deficiency (e.g. HIV, active chemotherapy or advanced cancer)
7. Scheduled elective surgery or other procedures requiring general anaesthesia during next 7 days
8. Participant who is terminally ill
9. Symptoms or signs suggesting that hospital admission is required (e.g. Completely unable to swallow, very systemically unwell, peritonsillar abscess)
10. Participant judged by the GP to require immediate antibiotics

11. History of severe affective disorders including steroid-induced psychiatric illness
12. British National Formulary (BNF) listed contra-indications to oral steroids
13. Existing symptoms that are also side effects of, oral steroids
14. Patients taking other interacting medication (e.g. Phenytoin and anti-coagulants). Clinicians will be asked to use the BNF and their clinical prescribing systems to check for interactions for all patients
15. Known dexamethasone allergy
16. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study
17. Involvement in another clinical trial of an investigational medicinal product in the last 90 days or any other research within the last 30 days
18. Recruiting primary care site is not the patients usual practice if the patient is not expecting to still be with the primary care site in one month (i.e. Temporary residents)
19. Previous TOAST participation
20. Patients able to be randomised by the end of the (working) day of presentation
21. Requirement for live vaccine in next 7 days

Date of first enrolment
12/04/2013

Date of final enrolment
27/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Health Care
Oxford
United Kingdom
OX1 2ET

Sponsor information

Organisation
University of Oxford

Sponsor details
Churchill Hospital
Old Road
Oxford

England
United Kingdom
OX1 2JD

Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The patient level data will be published on the EudraCT website after the publication of the initial results

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/09/2014		Yes	No
Participant information sheet	version V4	21/07/2016	21/07/2016	No	Yes
Results article	results	18/04/2017		Yes	No
HRA research summary			28/06/2023	No	No