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Do steroids speed recovery after drainage of a quinsy: a randomised, placebo-controlled trial

Submission date
23/07/2008

Recruitment status
Stopped

Registration date
27/08/2008

Overall study status
Stopped

Last Edited
28/11/2012

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Patrick Spielmann

Contact details
Department of Otolaryngology
Raigmore Hospital
Old Perth Road
Inverness
United Kingdom
IV2 3BG
+44 (0)1463 704000
patrickspielmann@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
07855752109

Study information

Scientific Title
Single dose dexamethasone following aspiration of a peri-tonsillar abscess: a randomised, placebo-controlled trial

Study objectives
Peri-tonsillar abscess is a common cause for emergency admission to an "Ear, Nose and Throat" (ENT) ward. In Raigmore there are 2-3 admissions per week with a quinsy. The standard management is needle aspiration under local anaesthetic, commonly performed in the ward treatment room. The patient would normally be admitted to the ward for intravenous antibiotics and fluid until they were able to resume a satisfactory oral intake. The length of admission depends very much on the speed of recovery and resumption of normal oral intake; this can vary from 6 hours - 48 hours.

Null hypothesis: There is no difference in the rate of recovery between patients given dexamethasone and those given saline after aspiration of a peri-tonsillar abscess.

Ethics approval required
Old ethics approval format

Ethics approval(s)
To be submitted to the Highland Research Ethics Committee as of 23/07/2008

Study design
Double-blind, randomised, placebo-controlled, single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Peri-tonsillar abscess (quinsy)

Interventions
Antibiotics (intravenous [IV]) + dexamethasone 8 mg (single dose) vs antibiotics (IV) + placebo

Standard antibiotics treatment would be benzyl-penicillin 1.2 g four times per day (qds) or clarithromycin 500 mg three times per day (tds) if allergic to penicillin.

Please note that this trial was stopped in February 2011 due to problems with recruitment and funding.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Time to resumption of oral intake of fluids and solids
2. Time to resolution of fever
3. Time to resolution of pain

Secondary outcome measures
Improvement in inter-incisor distance (i.e. mouth opening as surrogate marker for improvement), measured every 4 hours.

Overall study start date
01/10/2008

Completion date
01/10/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Patient with pus aspirated from peri-tonsillar abscess
2. Both males and females, age over 16
3. Minimum body weight of 40 kg

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
102

Key exclusion criteria

1. Children less than 16 may not be able to consent themselves to the study so will not be included
2. A body weight of less than 40 kg means the proposed dose of 8 mg dexamethasone is too high
3. Pregnancy
4. Inability to consent
5. Current symptomatic peptic ulcer

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Department of Otolaryngology
Inverness
United Kingdom
IV2 3BG

Sponsor information

Organisation
Raigmore Hospital (UK)

Sponsor details
c/o Mr Patrick Spielmann
Department of Otolaryngology
Old Perth Road
Inverness
Scotland
United Kingdom
IV23BG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05apdps44

Funder(s)

Funder type
Research organisation

Funder Name
Grant application has been submitted to the Otolaryngologic Research Society (http://www.ors.uk.net/) (UK). Decision pending as of 23/07/2008.

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration