

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

Submission date 23/07/2008	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/11/2012	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

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IV2 3BG

Sponsor information

Organisation

Raigmore Hospital (UK)

Sponsor details

c/o Mr Patrick Spielmann

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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