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Oral steroids for resolution of otitis media with effusion in children

Submission date
06/12/2012

Recruitment status
No longer recruiting

Registration date
07/12/2012

Overall study status
Completed

Last Edited
09/11/2018

Condition category
Ear, Nose and Throat

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Otitis media, also known as glue ear, is a common condition, especially in young children. Whilst we know that glue ear often gets better by itself, thousands of children each year experience prolonged hearing loss, which can lead to further problems. If hearing loss lasts longer than 3 months, children are usually offered hearing aids or a grommet operation. Several small research studies have suggested that treatment with oral steroids might help glue ear get better quicker. Oral steroids reduce inflammation in the body and are often used to treat conditions like asthma. However, the research done so far is not as good as we would like it to be, so we still can t say for definite whether a child with glue ear will benefit from treatment (e.g. improved hearing, glue ear gets better, no longer needs an operation for grommets) with an oral steroid. We want to answer these questions by testing the use of oral steroids (prednisolone sodium phosphate) in a research study being run from Cardiff University.

Who can participate?
Children aged between 2 to 8 years who have been referred to an Ear, Nose and Throat (ENT) outpatient clinic with symptoms of hearing loss due to glue ear for at least 3 months.

What does the study involve?
The study involves visiting the ENT clinic for a hearing assessment and taking home a short course of oral steroids to be given to the child once a day for 7 days, by dissolving it in liquid. We also ask parents to complete a diary recording their childs symptoms and any additional healthcare consultations their child has had over the subsequent 5 weeks. There will be follow up assessments at the ENT clinic at 5 weeks, 6 and 12 months.

What are the possible benefits and risks of participating?
A possible benefit of this study is that there may be a possibility that if the treatment works, the childs hearing will improve so that they will no longer need hearing aids or grommet surgery. In addition, the child will also have extra assessments and monitoring in the ENT clinic, which may be helpful. Participants in this study will be helping us answer questions about the treatment of glue ear in children that should result in better care for children with this condition in the future.

Taking part in the study will mean giving up some time. There is a chance that the child might develop side effects from the study treatment. However, side effects are uncommon with these treatments (especially when only taken for short periods of time), and are not usually serious.

Where is the study run from?
University Hospital of Wales (lead site) and nineteen hospitals in England and Wales (UK)

When is the study starting and how long is it expected to run for?
September 2013 to April 2017

Who is funding the study?
National Institute for Health Research - Health Technology Assessment Programme (UK)

Who is the main contact?
Dr Cherry-Ann Waldron
Waldronc@cardiff.ac.uk

Study website
http://www.ostrich-study.co.uk

Contact information

Type(s)
Scientific

Contact name
Dr Nick Francis

Contact details
Cardiff University
Institute of Primary Care and Public Health
School of Medicine
5th Floor, Neuadd Meirionnydd
Heath Park
Cardiff
United Kingdom
CF14 4YS

Additional identifiers

EudraCT/CTIS number
2012-005123-32

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 11/01/26; SPON1030-11

Study information

Scientific Title
A randomised double blind placebo controlled clinical trial using oral steroids for the resolution of otitis media with effusion (OME) in children

Acronym
OSTRICH

Study objectives
To determine the clinical and cost effectiveness of a 7-day course of oral prednisolone (steroid) on improving hearing loss over the short term in children with bilateral OME, as diagnosed at an ENT outpatient clinic, who have had symptoms attributable to OME present for at least 3 months, and current significant hearing loss (demonstrated by audiometry).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee, 13/01/2013 ref: 13/WA/0004

Study design
Randomised double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
http://www.ostrich-study.co.uk/parents.php

Health condition(s) or problem(s) studied
Otitis Media with Effusion (OME) or glue ear

Interventions
A 7-day course of oral soluble Prednisolone, as a single daily dose of 20mg for children aged 2-5 years or 30mg for 6-8 year olds and a matched placebo in the control group.

Intervention Type
Drug

Phase

Not Applicable

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

Primary outcome measure
Acceptable hearing at five weeks from randomisation (four weeks after conclusion of treatment), where acceptable hearing is defined as less than 20 dB averaged at 0.5, 1, 2 and 4 kHz in at least one ear in children aged 3-8 years, and less than 25 dB averaged at 0.5, 1, 2 and 4 KHz by sound field VRA in children aged under 3 years. These thresholds are based on national guidelines.

Secondary outcome measures
Current secondary outcome measures as of 17/12/2012:
1. Satisfactory hearing at 6 and 12 months, measured as above,
2. Tympanometry (using calibrated standardised tympanometers and modified Jeger classification Types B and C2)
3. Otoscopic findings
4. Healthcare consultations related to OME, and other resource use
5. Grommet surgery at 6, and 12 months
6. Adverse effects
7. Symptoms (reported by parent and/or child)
8. Functional health status (OM8-30)
9. Health related quality of life (PedsQL and HUI3)
10. Short and longer term cost effectiveness

Previous secondary outcome measures until 17/12/2012:
1. Satisfactory hearing at 3, 6, and 12 months, measured as above,
2. Tympanometry (using calibrated standardised tympanometers and modified Jeger classification Types B and C2)
3. Otoscopic findings
4. Healthcare consultations related to OME, and other resource use
5. Grommet surgery at 3, 6, and 12 months
6. Adverse effects
7. Symptoms (reported by parent and/or child)
8. Functional health status (OM8-30)
9. Health related quality of life (PedsQL and HUI3)
10. Short and longer term cost effectiveness

Overall study start date
01/03/2013

Completion date
27/04/2017

Eligibility

Key inclusion criteria
Updated 11/06/2015:
1. Aged 2-8 years (reached 2nd birthday and not yet reached 9th birthday)
2. Had symptoms of hearing loss attributable to OME for at least 3 months (or had audiometry

proven hearing loss for at least 3 months)
3. Diagnosis of bilateral OME made in an ENT clinic on the day of recruitment or during the preceding week
4. Audiometry confirming hearing loss of more than 20 dBHL averaged within the frequencies of 0.5, 1, 2, and 4 KHz in both ears by pure tone audiometry ear specific insert visual reinforcement audiometry (VRA) or ear specific play audiometry, or hearing loss of more than 25 dBHL averaged within the frequencies of 0.5, 1, 2, and 4 KHz by soundfield VRA or soundfield performance/play audiometry in the better hearing ear, on the day of recruitment or within the preceding 14 days
5. First time in the OSTRICH trial
6. Ability of parent/carer to understand and give informed consent

Updated 19/06/2013:
1. Aged 2-8 years (reached 2nd birthday and not yet reached 9th birthday)
2. Had symptoms of hearing loss attributable to OME for at least 3 months (or had audiometry proven hearing loss for at least 3 months)
3. Diagnosis of bilateral OME made in an ENT clinic on the day of recruitment or during the preceding week
4. Audiometry confirming hearing loss of more than 20 dBHL averaged within the frequencies of 0.5, 1, 2, and 4 KHz in both ears by pure tone audiometry ear specific insert visual reinforcement audiometry (VRA) or ear specific play audiometry, or hearing loss of more than 25 dBHL averaged within the frequencies of 0.5, 1, 2, and 4 KHz by soundfield VRA or soundfield performance/play audiometry in the better hearing ear, on the day of recruitment or in the preceding week
5. First time in the OSTRICH trial
6. Ability of parent/carer to understand and give informed consent
7. Does not already have grommets (ventilation tubes)

Original inclusion criteria:
1. Aged 2-8 years (reached 2nd birthday and not yet reached 9th birthday),
2. Had symptoms of hearing loss attributable to OME for at least 3 months (or had audiometry proven hearing loss for at least 3 months),
3. Diagnosis of bilateral OME made in an ENT clinic on the day of recruitment or during the preceding week,
4. Audiometry confirming hearing loss of more than 20 dB averaged at 0.5, 1, 2, and 4 KHz in the better ear by pure tone audiometry in children 3 years of age or more or hearing loss of more than 25 dB averaged over 0.5, 1, 2, and 4 KHz by sound field visual reinforcement audiometry (VRA) in children less than 3 years of age, on the day of recruitment or in the preceding week.

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
380

Key exclusion criteria
Updated 28/09/2015:
1. Children who are currently involved in another CTIMP or have participated in a CTIMP during the last 4 months
2. Children with current systemic infection or ear infection
3. Children with cleft palate
4. Children with Down's syndrome
5. Children with diabetes mellitus
6. Children with Kartagener's or Primary Ciliary Dyskinesia
7. Children with renal failure, hypertension or congestive heart failure
8. Children with confirmed, major developmental difficulties (e.g. are tube fed, have chromosomal abnormalities)
9. Children who have taken oral steroids in the preceding four weeks
10. Children who have had a live vaccine in the preceding four weeks if aged under 3 years old (not yet reached 3rd birthday)
11. Children with a condition that increases their risk of adverse effects from oral steroids (i.e. on treatment likely to modify the immune system or who are immunocompromised, such as undergoing cancer treatment)
12. Children who have been in close contact with someone known or suspected to have Varicella (chicken pox) or active Zoster (Shingles) during the three weeks prior to recruitment and have no prior history of Varicella infection or immunisation
13. Children with existing known sensory hearing loss
14. Children who already have grommets (ventilation tubes)
15. Children who are on a waiting list for grommet surgery and anticipate having surgery within 5 weeks and are unwilling to delay it

Updated 11/06/2015:
1. Children who are currently involved in another CTIMP or have participated in a CTIMP during the last 4 months
2. Children with current systemic infection or ear infection
3. Children with cleft palate
4. Children with Down's syndrome
5. Children with diabetes mellitus
6. Children with Kartagener's or Primary Ciliary Dyskinesia
7. Children with renal failure, hypertension or congestive heart failure
8. Children with confirmed, major developmental difficulties (e.g. are tube fed, have chromosomal abnormalities)
9. Children who have taken oral steroids in the preceding four weeks
10. Children who have had a live vaccine in the preceding four weeks
11. Children with a condition that increases their risk of adverse effects from oral steroids (i.e. on treatment likely to modify the immune system or who are immunocompromised, such as undergoing cancer treatment)
12. Children who have been in close contact with someone known or suspected to have Varicella (chicken pox) or active Zoster (Shingles) during the three weeks prior to recruitment and have no prior history of Varicella infection or immunisation

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13. Children who are on a waiting list for grommet surgery and anticipate having surgery within 5 weeks and are unwilling to delay it

Updated 17/12/2012:
1. Children with cleft palate
2. Children with Downs syndrome
3. Children with confirmed, major developmental difficulties (e.g. are tube fed, have chromosomal abnormalities)
4. Children with current systemic infection
5. Children with renal failure, hypertension or congestive heart failure
6. Children with diabetes mellitus
7. Children who have taken oral steroids in the preceding four weeks
8. Children with a condition that increases their risk of adverse effects from oral steroids (i.e. on treatment likely to modify the immune system or who are immunocompromised)
9. Children with no prior history of Varicella (Chicken Pox) infection or immunisation and who have been in close contact with someone known or suspected to have Varicella or active Zoster (Shingles) during the three weeks prior to recruitment
10. Children who are currently involved in another CTIMP or have participated in a CTIMP during the last 4 months

Original exclusion criteria:
1. Children with cleft palate
2. Children with Downs syndrome
3. Children with confirmed, major developmental difficulties (e.g. are tube fed, have chromosomal abnormalities)
4. Children who have taken oral steroids in the preceding four weeks
5. Children with a condition that increases their risk of adverse effects from oral steroids (i.e. on treatment likely to modify the immune system or who are immunocompromised including

insulin dependent diabetes mellitus)
6. Children with no prior history of Varicella (Chicken Pox) infection or immunisation and who have been in close contact with someone known or suspected to have Varicella or active Zoster (Shingles) during the three weeks prior to recruitment

Date of first enrolment
18/03/2014

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Pontyclun
United Kingdom
CF72 8XR

Study participating centre
Glangwili General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 2AF

Study participating centre

Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Singleton Hospital
Sketty Lane
Sketty
Swansea
United Kingdom
SA2 8QA

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
The GEM Centre
Neachells Lane
Wolverhampton
United Kingdom
WV11 3PG

Study participating centre
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Tunbridge Wells Hospital
Tonbridge Road
Tunbridge Wells
United Kingdom
TN2 4QJ

Study participating centre
Northwick Park Hospital
Watford Road
Harrow
United Kingdom
HA1 3UJ

Study participating centre
Royal National Throat, Nose and Ear Hospital
330 Gray's Inn Road
London
United Kingdom
WC1X 8DA

Study participating centre

Royal Stoke University Hospital
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
St Mary's Hospital
Parkhurst Road
Newport
Isle of Wight
United Kingdom
PO30 5TG

Study participating centre
East Surrey Hospital
Canada Avenue
Redhill
United Kingdom
RH1 5RH

Study participating centre
Blackpool Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre
Walsall Manor Hospital
Moat Road
Walsall
United Kingdom
WS2 9PS

Study participating centre
Worcester Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Sponsor information

Organisation
Cardiff University (UK)

Sponsor details
Research and Commercial Division
7th Floor
30-36 Newport Road
Cardiff
Wales
United Kingdom
CF24 0DE

Sponsor type
University/education

Website
http:www.cardiff.ac.uk

ROR
https://ror.org/03kk7td41

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nick Francis (FrancisNA@cardiff.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2016		Yes	No
Results article	results	18/08/2018		Yes	No
Basic results		23/08/2018	23/08/2018	No	No
Results article	results	01/11/2018		Yes	No
HRA research summary			28/06/2023	No	No