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Surgical excision versus antibiotic treatment for non-tuberculous mycobacterial cervicofacial lymphadenitis in children (CHIMED): a multicentre randomised controlled trial

Submission date
01/02/2006

Registration date
08/02/2006

Last Edited
21/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

[ ] 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

Study website
http://www.mycobacterie.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
945-02-019

Study information

Scientific Title

Acronym
CHIMED

Study objectives
Non-tuberculous mycobacteria (NTM) are a common cause of chronic cervicofacial lymphadenitis in children, especially between the age of 1 and 5 years.The disease is usually unilateral, occurring in the submandibular or preauricular area. The nodes suppurate and form a chronic sinus tract.

The optimal treatment of Non-Tuberculous Mycobacterial (NTM) cervical lymphadenitis in children has not been established. Until recently surgical excision was the standard treatment, but the number of reports of successful antibiotic treatment is increasing, questioning surgery as the preferred treatment. In this randomised, multicenter trial we compared surgical excision to antibiotic treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Medical Ethics Committee (MEC) ont he 1st November 2001 (ref: 00/182).

Study design
Randomised, multicentre clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Chronic cervicofacial lymphadenitis

Interventions
To compare surgical excision of involved lymph nodes with antibiotic therapy consisting of a three-month course of Clarithromycin and Rifabutin.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Clarithromycin, rifabutin

Primary outcome measure
Primary endpoint was cure, defined as regression of the enlarged lymph node by at least 75%, with cure of the fistula and total skin closure without local recurrence or de novo lesions at six months, as assessed by clinical and ultrasound evaluation.

Secondary outcome measures
Secondary outcome measures were surgical complications and side effects of the medication.

Overall study start date
01/09/2001

Completion date
01/12/2004

Eligibility

Key inclusion criteria
Children between 0 - 15 years old with a possible NTM lymphadenitis were referred by pediatricians, otolaryngologists, oral and maxillofacial surgeons and general practitioners from all over the country.

Inclusion criteria: an enlarged cervicofacial lymphadenitis for a period longer than three weeks, with negative serology for other infectious causes of chronic lymphadenitis (Cytomegalo Virus [CMV], Epstein-Barr Virus [EBV], adenovirus, bartonella and toxoplasmosis).

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Years

Upper age limit

15 Years

Sex
Both

Target number of participants
100 patients with NTM cervical lymphadenitis

Key exclusion criteria
Excluded were immunocompromised patients and patients using immunosuppressive drugs.

Date of first enrolment
01/09/2001

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
A1-1
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Sponsor details
Laan van Nieuw Oost-Indie 334
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Netherlands
2509 AE
+31 (0)70 3495259
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Sponsor type
Research organisation

Website
http://www.zonmw.nl

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (ref: 945-02-019)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		01/06/2004		Yes	No
Other publications		01/01/2005		Yes	No
Other publications		01/12/2005		Yes	No