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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

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)

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.

Key secondary outcome(s))
Secondary outcome measures were surgical complications and side effects of the medication.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 years

Upper age limit
15 years

Sex
All

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)

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

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

Study website	Study website	11/11/2025	11/11/2025	No	Yes