

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

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| <b>Submission date</b><br>01/02/2006   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>08/02/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>21/09/2007       | <b>Condition category</b><br>Circulatory System   | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <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

**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) on the 1st November 2001 (ref: 00/182).

### **Primary study design**

Interventional

### **Study design**

Randomised, multicentre clinical trial

### **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? |
|------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Other publications</a> |         | 01/06/2004   |            | Yes            | No              |
| <a href="#">Other publications</a> |         | 01/01/2005   |            | Yes            | No              |
| <a href="#">Other publications</a> |         | 01/12/2005   |            | Yes            | No              |

[Study website](#)

Study website

11/11/2025

11/11/2025

No

Yes