

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 21/09/2007	<b>Condition category</b> Circulatory System	<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

## Study website

<http://www.mycobacterie.nl>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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) on the 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

Den Haag

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2509 AE

+31 (0)70 3495259

bijlsma@zonmw.nl

**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?
<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