

# Mumps virus transmission in vaccinated populations, WP 2: short-term and long-term complications of mumps-associated orchitis in vaccinated men \* a prospective multicenter cohort trial

Published: 03-11-2011

Last updated: 29-04-2024

To assess short-term and long-term complications of mumps-associated orchitis in vaccinated men

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON36170

### Source

ToetsingOnline

### Brief title

Complications of mumps-associated orchitis in vaccinated men

### Condition

- Viral infectious disorders
- Male reproductive tract infections and inflammations

### Synonym

mumps, orchitis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** cryopreservation, mumps, orchitis, semen quality

## Outcome measures

### Primary outcome

Semen quality during initial non-infective phase of mumps orchitis and follow-up during at least 6 months period which can be lengthened if indicated.

### Secondary outcome

Levels of FSH, LH, testosterone, SHBG and Inhibin B during the abovementioned 6 month period.

If possible hormone levels and semen quality after one year.

## Study description

### Background summary

Despite a successful vaccination programme over many years, mumps has re-emerged. So far, outbreaks in fully vaccinated populations have been concentrated among young adults with close social interactions. In the Netherlands, an outbreak is ongoing since late 2009 among university students in various towns.

Therefore, the RIVM/Cib convened an Outbreak Management Team (OMT) on January 31st 2011 to discuss the situation, to assess additional control options, and to identify unresolved research questions. A major question is to improve understanding of the long-term clinical outcome of mumps-associated orchitis in vaccinated men with respect to their fertility.

### Study objective

To assess short-term and long-term complications of mumps-associated orchitis

in vaccinated men

## **Study design**

Observational study

## **Study burden and risks**

Participating in this study does not cause any risks for the subjects. The burden solely consists of the visits to the clinic and venapunctions.

## **Contacts**

### **Public**

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1105 AZ Amsterdam  
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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

## Inclusion criteria

All men of 18 or more prospectively diagnosed with acute uni- or bilateral mumps-associated orchitis in the Netherlands after vaccination are eligible for inclusion.

## Exclusion criteria

Exclusion criteria are the inability to ejaculate, the inability to provide written informed consent and risk factors in the medical history for decreased fertility (e.g. cancer, gonadal dysplasia, cryptorchidism etc).

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-02-2012

Enrollment: 30

Type: Actual

## Ethics review

Approved WMO

Date: 03-11-2011

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 14-02-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	23-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL36899.018.11