

# Does classic galactosemia affect male fertility?

Published: 16-02-2009

Last updated: 11-05-2024

Comparing fertility of male galactosemia patients to a control group

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

## Summary

### ID

NL-OMON33797

### Source

ToetsingOnline

### Brief title

Fertility of male Galactosemia patients

### Condition

- Endocrine disorders congenital
- Inborn errors of metabolism
- Sexual function and fertility disorders

### Synonym

Galactosemia, inherited metabolic disease of sugar metabolism

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Galactosemie Onderzoek Fonds

## Intervention

**Keyword:** Galactosemia, Hormones, Male Fertility

## Outcome measures

### Primary outcome

Semen parameters

Hormonal values

Children and/or time to pregnancy

### Secondary outcome

Not applicable

## Study description

### Background summary

Female classic galactosemia patients are known to have fertility problems. However, no systematic research on this topic in males has been done, leaving counseling concerning fertility unsecure.

### Study objective

Comparing fertility of male galactosemia patients to a control group

### Study design

A measure of fertility of male galactosemics and controls using:

- Preparing the mailed list of questions for the semi-standardized interview
- No ejaculation up to two days before the visit
- A visit to azM with
  - o A semi-standardized interview
  - o Two questionnaires concerning quality of life and course of life
  - o A physical examination
  - o A blood withdrawal (20 ml of blood)
  - o An ultrasound of the testes
  - o Semen production through masturbation

This visit will take maximum 1/2 day. The preparation of the

questionnaire is estimated to be maximum one hour

- About three months after the visit, a new semen sample is either picked up at the patient's house by the researcher, or brought to azM or a nearby hospital by the patient

### **Study burden and risks**

Physical: only venapunction

Psychological: will be thoroughly addressed.

## **Contacts**

### **Public**

Academisch Medisch Centrum

Postbus 5800  
6202 AZ Maastricht  
Nederland

### **Scientific**

Academisch Medisch Centrum

Postbus 5800  
6202 AZ Maastricht  
Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Patients:

Galactosemia, diagnosed by GALT activity measurement or DNA analysis

Male;Controls:

Healthy male

## Exclusion criteria

A known congenital or acquired disease or disorder negatively affecting male fertility

## Study design

### Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2009
Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	16-02-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## 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	NL22703.068.08