

# Protocol optimization of the quantification of gait using the GAITRite in m.3243A>G carriers

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Protocol optimization for the GAITRite in m.3243A>G carriers

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Metabolic and nutritional disorders congenital
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON42798

### Source

ToetsingOnline

### Brief title

GAITRite in m.3243A>G

### Condition

- Metabolic and nutritional disorders congenital

### Synonym

disturbance in energy metabolism, mitochondrial disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** gait, GAITRite, m.3243A>G, mitochondrial disease, outcome measure

## Outcome measures

### Primary outcome

The parameters calculated by the GAITRite

### Secondary outcome

Muscle power mm. quadriceps

3 min walking test

Berg Balance Scale

Balance (forceplatform)

## Study description

### Background summary

There is a quest for sensitive outcome measures for clinical trials in m.3243A>G carriers, the most frequent mutation of mtDNA.

Gait abnormalities are frequently reported by patients carrying the m.3243A>G mutation.

The group from Newcastle reported abnormal gait in a small cohort of m.3243A>G carriers using the GAITRite

### Study objective

Protocol optimization for the GAITRite in m.3243A>G carriers

### Study design

Observational study with non invasive measurements testing 3 different protocols and their test-retest reliability and deviation from healthy controls

### Study burden and risks

Limited burden

No risk

Large group relatedness since this study is a preparation for the phase 2 trial in this population.

## Contacts

### Public

Selecteer

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NL

### Scientific

Selecteer

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Carrier of the m.3243A>G mutation

Older than 18 years; Healthy = no conditions leading to abnormal gait (orthopedic, neurological or neuromuscular disorders)

## Exclusion criteria

Orthopedic problems interfering with gait  
Not able to walk for 3 minutes

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2016
Enrollment:	100
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-01-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## 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**

CCMO

### **ID**

NL56121.091.15