# Development, optimalisation and validation of the exercise diagnostics for functional iliac flow limitations in endurance athletes: blood pressure measurement, pedal force measurement and near infrared spectroscopy

Submission date 14/02/2006	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 14/02/2006	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 03/07/2009	<b>Condition category</b> Other	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

**Plain English summary of protocol** Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers NTR526

## Study information

Scientific Title

#### **Study objectives**

The use of a new protocol of exercise testing with use of blood pressure measurement, near infrared spectroscopy and pedal force measurement will improve the diagnostic value of the current decision algorithm used to diagnose functional iliac flow limitations in endurance athletes.

Ethics approval required

Old ethics approval format

**Ethics approval(s)** Received from the local medical ethics committee

**Study design** Randomised active controlled parallel group trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

**Study type(s)** Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied Functional iliac flow limitations

#### Interventions

Blood pressure measurements, pedal force measurements and near infrared measurements during and after exercise testing in both patients and in healthy test subjects

Intervention Type Other

**Phase** Not Specified

#### Primary outcome measure

Improvement of sensitivity and specificity of diagnostic tools in diagnosing sports related flow limitations of the iliac arteries

**Secondary outcome measures** No secondary outcome measures

Overall study start date 01/09/2005

Completion date 31/12/2007

## Eligibility

**Key inclusion criteria** Athletes/patients diagnosed with functional iliac flow limitations and healthy athletes

**Participant type(s)** Patient

**Age group** Adult

**Sex** Both

**Target number of participants** 210

**Key exclusion criteria** Does not comply with the above inclusion criteria

Date of first enrolment 01/09/2005

Date of final enrolment 31/12/2007

#### Locations

**Countries of recruitment** Netherlands

Study participating centre

**Maxima Medisch Centrum** Veldhoven Netherlands 5500 MB

#### Sponsor information

**Organisation** Maxima Medical Center (Netherlands)

Sponsor details P.O. Box 7777 Veldhoven Netherlands 5500 MB +31 (0)40 8888000 info@mmc.nl

#### Sponsor type

Not defined

ROR https://ror.org/02x6rcb77

#### Funder(s)

Funder type Not defined

**Funder Name** Not provided at time of registration

## **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