ISRCTN84883192 https://doi.org/10.1186/ISRCTN84883192

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

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
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Sponsor information

Organisation
Maxima Medical Center (Netherlands)

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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