Tarsometatarsal (Lisfranc) luxation fractures

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Primairy aim:To determine the AOFAS Midfoot functional outcome score after operative or non-operative treatment of patients whou sustained a Lisfranc luxation fracture, with a minimum follow-up of 2 years.Secundairy aims:1. To determine the effect...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fractures
Study type	Observational invasive

Summary

ID

NL-OMON33308

Source
ToetsingOnline

Brief title
Lisfranc luxation fractures

Condition

- Fractures

Synonym
Lisfranc luxation fractures, midfoot fractures

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds NutsOhra

Intervention

Keyword: Lisfranc, Luxation fractures, Plantar pressure analyses, Treatment outcome

Outcome measures

Primary outcome

American Orthopaedic Foot Ankle Society (AOFAS) midfoot score

Secondary outcome

- ShortForm-36 (SF-36)

- Visueal Analogue Scale (VAS) for patient satisfaction

- Radiographic evaluation

- Pressure characteristics at different parts of the foot

Study description

Background summary

There is stil controversy concerning the best management approach for Lisfranc luxation fractures. The choice is between conservatieve treatment using Plaster of Paris, or operative treatment (open surgery, percutaneous approach, primary arthrodesis). Likewise, the type of osteosynthesis material to be used (Kirschner wires versus screws) is still undecided. Lisfranc luxation fractures are considered as unstable fractures. Patients sometimes experience complaints for a prolonged period of time, and a delayed or inadequate could have detrimental consequences. Therefore, additional research is needed in order to identify the best treatment strategy.

Study objective

Primairy aim:
To determine the AOFAS Midfoot functional outcome score after operative or non-operative treatment of patients whou sustained a Lisfranc luxation fracture, with a minimum follow-up of 2 years.

Secundairy aims:
1. To determine the effect of operative or non-operative treatment on the health-related quality of live (SF-36) and overall satisfaction with the

treatment outcome (VAS) of patients who sustained a Lisfranc luxation fracture .
2. To determine the prognostic value oof the degree of fracture reduction (anatomic reduction or > 2 mm dislocation) and the type of osteosynthesis material (Kirschner wires or screws) on the functional outcome score.
3. To determine the pressure characteristics of the affected foot versus the contralateral side in patients treated operatively or non-operatively.

It is expected that patients with surgically managed fractures will a report higher outcome score and less deviations in pressure characteristics than patients with conservatively managed fractures.

Study design

Retrospective cohort study

Study burden and risks

Patients will be asked to come to the outpatient department once. During that visit, three X-rays will be taken both feet (AP, 3/4 and lateral image).
Patients will be asked to complete three questionnaires (AOFAS midfoot, SF-36, and VAS) and to walk on a pressure mat (2 meter) five times. Due to the radiation exposure of the X-rays, pregnant women are excluded from participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Isolated Lisfranc luxation fracture (confirmed on X-ray or CT)
- Age 18 years or older, without upper age limit
- Informed consent
- Living in the Netherlands

Exclusion criteria

- Intra-articular calcaneal fracture, talus fracture luxation fracture of the Chopart joint
- Age <18 years
- No permanent address
- Patient not ambulant (e.g., wheelchair and bed-bound)
- No informed consent
- Insufficient comprehension of the Dutch language, in the opinon of the researcher

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	19-04-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26344.078.08