Use of a reinforced injectable calcium phosphate bone cement in the treatment of Tibial Plateau fractures

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The objective of the study is to observe the performance of a new implant during and after surgery. The information from this project will help develop new techniques for using this product and be used to train other surgeons.

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

Summary

ID

NL-OMON34737

Source
ToetsingOnline

Brief title
Norian Drillable

Condition

- Fractures

Synonym
tibia plateau fracture

Research involving
Human

Sponsors and support

Primary sponsor: Synthes GmbH
Source(s) of monetary or material Support: Synthes GmbH;Zwitserland

Intervention

Keyword: Norian Drillable, tibia plateau

Outcome measures

Primary outcome

Duration of the surgery (operating room time)

Blood loss

Complications

Ease of use

Secondary outcome

To define the clinical and radiographic outcome of using Norian Drillable by

evaluating:

1. fracture stabilization and

2. patient function and pain over time.

Study description

Background summary

The new implant is a paste that is used to temporarily replace missing bone. The paste will harden after it is implanted, but it will be replaced by natural bone over time. The new implant is an improved version of a paste that is commonly used for the same purpose.

Study objective

The objective of the study is to observe the performance of a new implant during and after surgery. The information from this project will help develop new techniques for using this product and be used to train other surgeons.

Study design

Observational study without comparison group, a case-series

Intervention

All patients will receive Norian Drillable to fill the bone void in the tibia plateau fracture

Study burden and risks

The potential medical risks associated with the new implant are expected to be the same as the general risks associated with implanting this type of product. Previous studies with similar implants reported:

Local inflammation - the area around the implant becomes painful and swollen
Infection - the implant becomes infected
Material migration - movement of the implant from the intended implant site into the surrounding soft tissue
Extrusion - small pieces of implant may cut the skin
Lack of hardening - the material does not harden as anticipated
Material remaining after healing - the implant will dissapear over a period of years, but the fracture usually heals sooner

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

1.Subjects with closed tibial plateau fractures classified as OTA B2, B3 or C3 resulting in a bone void.
2.At least 18 years of age.
3.Psychosocially, mentally and physically able to fully comply with this protocol including adhering to follow-up schedule and requirements and filling out forms.

Exclusion criteria

1.Critically ill
2.Mentally ill or mentally disordered
3.Wards of the state
4.Prisoners
5.Refugees
6.In an employer - employee, teacher - student relationship or any other dependant with the researchers or their associates
7.Active or suspected infection - systemic or local
8.Gustillo classification of 2 or 3
9.Bilateral tibial plateau fractures when both fracture patterns extend into the joint
10.Have an existing calcium metabolism disorder (e.g. hypercalcemia)
11.Chronic renal disease/renal failure
12.Insulin dependent diabetes
13.Taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids).
14.Rheumatoid arthritis or other autoimmune disease.
15.Systemic disease including AIDS, HIV, hepatitis.
16.Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless he/she has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years.
17.Subjects involved in other studies within the last month, prior to screening.
18.Pregnant or interested in becoming pregnant in the next 18 months. Females of child-bearing potential must use an acceptable method of contraception during trial participation.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Norian Drillable
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-01-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	ND-AUS-01
CCMO	NL31606.100.10