Can changes in joint fluid explain cartilage repair after joint distraction?

Published: 06-05-2015
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To study the change in joint homeostasis induced by knee joint distraction.

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

Summary

ID

NL-OMON47444

Source
ToetsingOnline

Brief title
Joint Fluid Sampling During Knee Distraction

Condition

- Joint disorders

Synonym
joint degeneration, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Foreum;fonds van de Eular (en mogelijk; aanvraag loopt nog Reumafonds en UK arthrits foundation)

Intervention

Keyword: joint fluid, joint homeostasis, knee distraction, knee osteoarthrits

Outcome measures

Primary outcome

Change in joint homeostasis. Joint homeostasis is a complex of soluble mediators and cells responsible for the integrity (e.g. nutrition, maintenance, and turnover) of the cartilage tissue (note: cartilage is not vascularised and thus for its mediators dependent on exchange with the joint fluid). There will be a focus on changes in i) growth factors, ii) proteases, iii) proinflammatory cytokines, iv) pro-inflammatory cells, and v) stem cells.

Secondary outcome

NA

Study description

Background summary

Knee joint distraction (KJD) in treatment of severe knee osteoarthritis (OA) has shown significant prolonged (at least 5 years) clinical benefit (decreased pain and increased function) in about 80% of patients. Importantly, KJD results in cartilage tissue repair (increase in thickness and volume observed by X-ray, MRI, and serum/urine biochemical marker analyses. This cartilage tissue repair is considered to underlay the prolonged clinical benefit after this relatively short treatment. Cartilage tissue repair, being the goal of many research groups, is considered unique as cartilage tissue repair has for a long time been considered very difficult if not impossible. It is anticipated that this unique tissue repair activity is caused by an altered joint homeostasis (mechanically and biochemically) as a result of distraction.
At present knee joint distraction becomes implemented in clinical practice. In 4 institutes in the Netherlands (and some institutes abroad) it is performed now in regular clinical practice. However, there is no knowledge on the mechanisms underlying the cartilage tissue repair upon this treatment. Such knowledge is of significant importance as it will provide tools for (improvement of) cartilage tissue repair strategies in osteoarthritis. The obtained knowledge might be of help for many attempts focusing at cartilage tissue repair studied by the many groups worldwide.

Study objective

To study the change in joint homeostasis induced by knee joint distraction.

Study design

Pilot, observational study, with invasive (joint fluid sampling) measurements.

Study burden and risks

Benefit: Patients will be treated in regular practice with knee joint distraction. Patients have no direct benefit of participating in the study. Results will elucidate the underlying mechanisms by which cartilage tissue repair can be supported (as observed during joint distraction) and may provide tools for improvement of (novel) cartilage repair strategies. Joint distraction is unique in this respect because there are no other treatments that result in cartilage tissue repair, and as such the only way to unravel such mechanisms (from insight-out).

Burden: At baseline (under anaesthesia during placing of the distraction device), half way (3±1 weeks post distraction, under local anaesthesia), and at the end (week 6; under anaesthesia when the frame is removed), 2 cc joint fluid (less than 10% of the joint fluid present) will be obtained by needle aspiration using a syringe. The 1st and 3rd needle aspiration will be under anaesthesia (as performed in regular clinical practice) without discomfort. The 2nd needle aspiration (under local skin anaesthesia with Lidocaine will provide some discomfort. However, in general the knee joint is characterised by (a slight) effusion during distraction and an extra joint space of ~5 mm because of distraction is present, which will significantly facilitate aspiration.

Risks: a) A potential, (although considered very small) chance on a diminished clinical benefit because of interference in the joint homeostasis during joint distraction. b) A potential, (although considered small) chance on an intra-articular infection because of the three intra-articular needle punctures. However, 2 of these 3 are taken under full surgical conditions (operating rooms). The remaining one is a general procedure in orthopaedics and rheumatology practice performed at the out-patients clinics, although for this study performed when a distraction frame is present. As such, optimal infection prevention is needed and good monitoring will be performed. In case intra-articular infection would occur, regular clinical care is indicated.

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

Patients with knee joint degeneration (osteoarthritis) eligible in regular clinical practice for knee joint distraction.
For the study specific: written IC based on PIF for 3 intra-articular joint fluid needle aspirations.

Exclusion criteria

Unable to undergo knee joint distraction in regular clinical practice.
For the study specific exclusion criteria: unable to provide written IC based on written (PIF) and oral study information for 3 intra-articular joint fluid needle aspirations.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-01-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	06-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-05-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-03-2019
Application type:	Amendment
Review commission:	METC NedMec

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	NL51539.041.15