Instant MSC Product accompanying Autologous Chondron Transplantation (IMPACT) for focal articular cartilage lesions of the knee; feasibility and safety

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON37740

Source
ToetsingOnline

Brief title
IMPACT

Condition

- Tendon, ligament and cartilage disorders

Synonym
Cartilage defect/ lesion.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cartilage defect, knee, MSCs and chondrons, One-stage

Outcome measures

Primary outcome

The primary objective of this study is clinical safety. Therefore, the main study parameter will be newly developed, or worsening of, existing AEs (see section 8.2 for definitions). A full, per patient, description of each AE will be recorded including the nature, date and time of onset, date or resolution, determination of seriousness, severity, action taken, outcome and causality to study treatment. Specific AEs of interest (see section 8.2.4 for definition) will be filed in a similar manner as AEs using separate scoring forms. If indicated, tissue vigilance will be reported to the Transfusion Reaction in Patients (TRIP) National Hemovigilance Office.

Secondary outcome

The secondary study parameter will be the clinical improvement and quality of life after 6, 12 and 18 months as measured with, subscales of, the KOOS and the EQ5D, respectively.

Study description

Background summary

Articular cartilage defects in the knee have poor intrinsic healing capacity and may lead to functional disability and osteoarthritis. Cartilage cell therapy using autologous chondrocyte implantation has been established as the first advanced treatment therapy medicinal product. Although this technique has

achieved good mid-term results, it is a costly and extensive two-stage procedure which is limited by the number of chondrocytes obtained by biopsy and the dedifferentiation resulting from the expansion phase. Therefore, there is a need for improvement. A new cartilage repair technique should aim at decreasing surgical trauma, lowering complexity, improving logistics and cost-effectiveness while retaining or improving clinical outcome. Direct contact between mesenchymal stromal cells (MSCs) and dedifferentiated articular chondrocytes in vitro showed improvement of the chondrogenic phenotype of dedifferentiated articular chondrocytes. In addition, preserving the pericellular matrix of chondrocytes improves cartilage formation. These chondrons (chondrocytes with their pericellular matrix) have shown improved cartilage formation when combined with MSCs. These cells can be mixed with a widely used, commercially available, fibrin cell carrier and applied to the cartilage lesion within one surgical procedure, using a minimally invasive and eventually arthroscopic technique. This will reduce patient morbidity and improve patient care through immediate transplantation of a potent cell-based cartilage product. Therefore, we now propose the clinical evaluation in a phase I/II prospective monocenter study of the IMPACT for treatment of articular cartilage defects of the knee to prove clinical safety and feasibility.

Study objective

The primary objective of this study is to examine clinical safety and feasibility of the IMPACT therapy. The secondary objective is to measure the level of clinical improvement and quality of life at 6, 12 and 18 months. The tertiary objective of this study is to examine parameters of structural repair one year after treatment. The quaternary objective is to assess the healthcare use and costs related to the procedure as well as the health-related work leave during the study period.

Study design

This is a phase I/II prospective monocenter study, investigating the feasibility and safety of a new ATMP-product for isolated articular cartilage lesions

Intervention

One-stage surgery using the Instant MSC Product accompanying Autologous Chondron Transplantation (IMPACT)

Study burden and risks

Potential risks: graft failure and/ or migration or foreign body responce, tissue hypertrophy (excessive growth of new tissue), and general knee surgery related risks such as surgical site infection, arthralgia, joint crepitation,

swelling, effusion, chondropathy, synovitis, deep-vein thrombosis, pulmonary embolism, haemarthrosis and arthrofibrosis. See section 7.2 for definitions of AEs.

Regarding the burden for patients, this procedure is a one-stage procedure which is an advantage compared to the conventional two-stage procedure. For the participation 3 additional visits to the hospital are required in which the patient will be subjected to a physical exam as well as be asked to complete the questionnaires. Prior to treatment and at at the visit at 12 months, a contrast MRI scan will be obtained. In addition, at twelve months an arthroscopy with biopsy will be performed.

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 aged 18-45 with a cartilage defect in the femoral condyle or trochlea sized 2-8 cm2

Exclusion criteria

Patients with other dieases of the knee joint such as osteoarthritis, inflammatory disease (rheumatoid arthritis, metabolic joint disease, psoriasis and gout and septic arthritis), malalignment and patients with a prior total menisectomy.

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):	10-04-2013
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	28-08-2012

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-04-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	22-11-2013
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	06-05-2014
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2012-001570-29-NL
CCMO	NL40142.000.12

Study results

Date completed:	10-02-2016
Actual enrolment:	35