ISRCTN69838191 https://doi.org/10.1186/ISRCTN69838191

New bone marrow aspirate therapy for managing knee osteoarthritis

Submission date
29/11/2021

Recruitment status
No longer recruiting

Registration date
30/11/2021

Overall study status
Completed

Last Edited
03/01/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Osteoarthritis is the most common form of arthritis, and the knee is one of the most commonly affected joints. Current treatment guidelines are focused on treatment of the symptoms but no progress has been made regarding the real mechanism of the disease. Carboplasty is a new technique that consists of applying the patient's own bone marrow aspirate directly to the union between the bone and the cartilage to delay the progression of the disease, repair the damage and hopefully regenerate the cartilage. The aim of this study is to evaluate the effectiveness and safety of this new technique by comparing it to a placebo (dummy treatment).

Who can participate?
Patients aged 30-80 years with knee osteoarthritis who have failed medical treatment and with evidence of bone lesions on MRI scans

What does the study involve?
The study involves symptom questionnaires and an MRI scan performed before the treatment. All patients are randomly allocated to either the placebo group or the carboplasty group. Once assigned to a specific treatment (without the patient knowing which treatment) patients undergo the procedure under sedation. After the treatment, all patients are followed up to 1 year after the procedure where the symptom questionnaires and the MRI scan are repeated. Throughout the follow-up, patients are constantly contacted to check for any adverse event to the procedure, and if present, they are treated.

What are the possible benefits and risks of participating?
Carboplasty is a new technique with promising results in previous studies. Probable risks related to the procedures are knee pain after the intervention, minor swelling of the knee, minor bleeding, complications from anesthesia, wound infections, and neurovascular lesions (problems that affect the blood vessels in the brain and spinal cord) during the procedures. However, these complications were minimized by having a clean and controlled environment in the operating room.

Where is the study run from?
Ruby Clinic Hall (India)

When is the study starting and how long is it expected to run for?
January 2013 to June 2017

Who is funding the study?
The Vad Foundation (USA)

Who is the main contact?
Dr Vijay B. Vad
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Carboplasty for managing knee osteoarthritis: a placebo-controlled randomized trial

Study objectives
Carboplasty leads to better clinical and magnetic resonance imaging outcomes than placebo on patients with knee osteoarthritis (OA) and edema-like marrow signals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/08/2014, Poona Medical Research Foundation Ethics Committee (Ruby Hall Clinic, 40 Sassoon Road, Pune, India 411001; +44 (0)20 66455582; reenew20@gmail.com), ref: VAD-01 /RB/001

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Patients are randomized with a 1:1 ratio to either carboplasty or placebo. Allocation was performed by a research assistant blinded to the treatment using a computerized random number generator.

Both procedures are performed under sterile conditions, using IV sedation, and with fluoroscopic guidance. Patients in the placebo group have the PeCaBoo system inserted into the inferior and superior bone-cartilage interface (BCI) by itself, with no bone marrow aspirate being applied neither in the BCI nor intra-articular.

A reverse microfracture bio-enhanced with core decompression procedure is performed on the patients in the carboplasty group. 9 cc of tibial marrow aspirate is obtained from the proximal tibia using the PeCaBoo system in a syringe preloaded with 1 cc of heparin. Using the same syringe and the PeCaBoo system, 2 cc out of the 10 cc are injected into the superior BCI on the femoral condyle where the bone edema is detected on MRI. Another 2 cc is injected into the inferior BCI on the tibia ipsilateral to the femoral condyle. The remaining 6 cc is injected into the knee joint using the medial approach and a 22-gauge needle.

Patients are instructed not to exercise for 2 days after the intervention. After day 3, patients are allowed to use a stationary bike for 30 minutes every day followed by 15 minutes of cryotherapy. Complete return to activity is permitted after 1 month.

Intervention Type
Procedure/Surgery

Primary outcome measure
Knee pain evaluated by the visual analog scale of pain from 0 to 10 at baseline and 1 year after treatment

Secondary outcome measures
1. Pain related to different activities measured using the Knee injury and Osteoarthritis Outcome Score (KOOS) from 0 (really symptomatic) to 100 (asymptomatic) at baseline and after 1-year post-treatment
2. Morphological evaluation and bone marrow edema measured using magnetic resonance imaging at baseline and after 1-year post-treatment
3. Adverse events measured using a questionnaire and self-reported monthly for 1-year post-treatment
4. Treatment failure, defined as total knee arthroplasty due to refractory pain despite the treatment, at 1-year post-treatment

Overall study start date
01/01/2013

Completion date
06/06/2017

Eligibility

Key inclusion criteria
1. Patients willing and able to give informed consent
2. Age 30-80 years
3. Body mass index <35 kg/m²
4. Symptomatic knee OA grade II or III diagnosed by radiographic Kellgren and Lawrence
5. History of at least 6 months of conservative treatment and no improvement of symptoms*

6. Evidence of edema-like marrow signals by MRI
7. Patients medically able to undergo carboplasty
8. Patients willing and able to follow the rehabilitation protocol

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
36

Total final enrolment
50

Key exclusion criteria
1. Prior history of articular infection
2. Prior history of knee arthroscopy
3. Chronic use of anticoagulation
4. Patients diagnosed with cancer or currently undergoing chemotherapy
5. Patients unable to undergo MRI
6. Patients who are pregnant or intend to become pregnant during the first year after initial enrollment
7. History of autoimmune disease
8. Evidence of HIV or chronic hepatitis B or C viral infections
9. Current drug or alcohol abuse
10. Patients deemed by the investigator as unlikely to comply with the protocol
11. Vascular or neurological abnormalities affecting the lower extremities
12. Any form of inflammatory arthritis
13. Uncontrolled systemic disease (diabetes mellitus, hyperthyroidism, etc)

Date of first enrolment
01/01/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
India

Study participating centre
Ruby Hall Clinic
40, Sasoon Rd, Sangamvadi

Pune
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Sponsor information

Organisation
The VAD Foundation

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Sponsor type
Charity

Website
http://www.nonprofitfacts.com/NY/Vad-Foundation.html#ixzz7DdLpHLeT

Funder(s)

Funder type
Charity

Funder Name
The VAD Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The complete study protocol will be available once it is published. The researchers plan to get the protocol published next year (2022).

Intention to publish date
06/06/2022

Individual participant data (IPD) sharing plan

For access to the datasets please contact Dr Antonio Madrazo-Ibarra at amadrazoi@live.com. Data including databases, statistical analysis, informed consent forms, and symptom questionnaires can be shared upon request. This information will only be shared for research or review purposes.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/12/2022	03/01/2023	Yes	No