Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Therapeutic and immunogenic effects of implanting Wharton’s jelly-derived mesenchymal stem cells into the knee joint of osteoarthritis patients in grade 2 & 3 Kellgren Lawrence scale: an interventional randomized double-blind placebo controlled clinical trial, phase I

Protocol summary

Study aim

Examination of therapeutic and immunogenic effects of implanting Wharton’s jelly (umbilical cord)-derived mesenchymal stem cells into knee joint of osteoarthritis patients in grade 2&3 Kellgren Lawrence scale

Design

Interventional randomized double-blind placebo controlled clinical trial with a parallel group design of 40 patients in phase I. SAS 9.1 software will be used for randomization.

Settings and conduct

This study evaluates the efficiency of allogenic mesenchymal stem cells (produced under GMP standard) in osteoarthritis treatment being tested on patients referring to Chamran Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria include Knee osteoarthritis (grade 2 & 3 Kellgren Lawrence scale), knee and femur malalignment of less than 30 degree, VAS pain level of 4-7 measured 24 hours prior to referral, Age between 40-65 years, Female/Male and Given informed consent. Exclusion criteria include Inflammatory and Autoimmune disorders, Cancer or severe diseases, Metabolic disorders, Immunodeficiency, Contagious viral infections, Psychological disorders, Liver or kidney failure, BMI of more than 30 Kg/m2, Fever, Oral corticosteroids intake during the last 4 weeks, Corticosteroids infusion during the last 6 months, Hypersensitivity to proteins or other components of culture medium, Blood clotting disorders, Pregnant women or women planning for a pregnancy during the last 1 year, Participating in another clinical trial at the same time, Septic arthritis and Addiction to drug/ alcohol/ painkillers/ or anesthetic substance.

Intervention groups

The intervention group will receive hyaluronic acid (XHA) scaffold loaded with Wharton's jelly-derived mesenchymal stem cells and the control group will only receive HXA scaffold.

Main outcome variables

Improvement of walking pattern, physical activity and ability to perform daily routines, and reduction of inflammation and pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210103049925N1**
Registration date: **2021-05-20, 1400/02/30**
Registration timing: **prospective**

Last update: **2021-05-20, 1400/02/30**
Update count: **0**

Registration date

2021-05-20, 1400/02/30

Registrant information

Name

Amin Kamrani Rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2795 2613

Email address

amin_kamranirad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic and immunogenic effects of implanting Wharton’s jelly-derived mesenchymal stem cells into the knee joint of osteoarthritis patients in grade 2 & 3 Kellgren Lawrence scale: an interventional randomized double-blind placebo controlled clinical trial, phase I

Public title

The effect of mesenchymal stem cells on osteoarthritis recovery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Knee osteoarthritis (OA) (grade 2 & 3 Kellgren Lawrence scale) Radiography indicative of knee and femur malalignment of less than 30 degree Pain level of 4-7 measured in visual analog scale (VAS) 24 hours prior to referral Age range of 40-65 years Female/Male Given informed consent

Exclusion criteria:

Inflammatory disorders Metabolic disorders (e.g : diabetes mellitus) Autoimmune diseases Immunodeficiency Cancer or other severe diseases Contagious viral infections Psychological disorders History of renal or hepatic failure Body mass index (BMI) >30 Fever Oral corticosteroids in the last 4 weeks Injection of corticosteroids in the last 6 months History of protein or other related allergies Coagulation disorders Pregnancy or planning for pregnancy in the last 12 months Participating in other clinical trials at the same time Septic arthritis Addiction to opium, alcohol, painkillers, and/or anesthetics

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using SAS 9.1 software, a random number table will be designed. The participants will randomly receive the random numbers placed in similar, sealed, and non-transparent envelopes. They will choose an envelope once visiting the doctor. Accordingly, the participants will be divided into control and intervention groups. The envelopes will be kept with a researcher who is neither participating in the study nor is aware of the study design until data collection phase. Only in case of emergency and sever complications, the principal project executor asks the researcher to open the related envelope.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Chamran Hospital

Street address

Chamran Hospital, Langari St., Nobonyad Sq., Pasdaran Ave., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1693715817

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.CHAMRANHOSPITAL.REC.1400.001

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Lysholm score

Timepoint

3 months post injection

Method of measurement

Lysholm questionnaire

2

Description
International Knee Documentation Committee score
Timepoint
3 months post injection
Method of measurement
International Knee Documentation Committee (IKDC) Questionnaire

3

Description
Disability index
Timepoint
3 months post injection
Method of measurement
Health Assessment Questionnaire

4

Description
Pain index
Timepoint
3 months post injection
Method of measurement
Visual Analogue Scale questionnaire

5

Description
Cartilage thickness
Timepoint
3 months post injection
Method of measurement
Magnetic resonance imaging

6

Description
Range of motion
Timepoint
3 months post injection
Method of measurement
Goniometer

7

Description
Walking distance in six minutes
Timepoint
3 months post injection
Method of measurement
Meter

Secondary outcomes

1

Description
Side effects
Timepoint
3 months post injection
Method of measurement
Clinical symptoms, questionnaire, peripheral blood and urine samples

Intervention groups

1

Description
Intervention group: Receiving 40 million Wharton's jelly-derived mesenchymal stem cells loaded on 5CC hyaluronic acid via injection into knee joint (20 patients). All the required elements and ingredients such as cells are provided by Celltech Pharmed company. In this study, only one intra-articular injection will be done into knee using sterile G22 syringe and the patients will be followed-up for 3 months post injection.
Category
Treatment - Other

2

Description
Control group: Receiving 5CC hyaluronic acid via injection into knee joint (20 patients). All the required elements and ingredients are provided by Celltech Pharmed company. In this study, only one intra-articular injection will be done into knee using sterile G22 syringe and the patients will be followed-up for 3 months post injection.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Amin Kamrani Rad
Street address
Chamran Hospital, Langari St., Nobonyad Sq., Pasdaran Ave., Tehran, Iran
City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Celltech Pharmed Company

Full name of responsible person
Yunes Panahi

Street address
CellTechPharmed Co., Tolid Darou Co., Hamidreza Yadegar St., Meybod St., Tolid Darou, Tehran,. Iran

City
Tehran

Province
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Postal code
۱۳۷۱۶۱۶۳۱۴

Phone
+98 21 6735 7000

Email
info@celltech.co

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Celltech Pharmed Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Yunes Panahi

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
Baqiyatallah University of Medical Sciences, Mollasadra Ave., Vanak Square, Tehran, Iran

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Contact

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Full name of responsible person
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Position
Professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All the data and observations will be published after analysis.

When the data will become available and for how long

After follow up and data gathering, evaluation of immunogenicity and efficiency of cell injection, and writing the paper which is approximately 3 months after follow up, the data file will be released.

To whom data/document is available

Activity in cell therapy domain is the only parameter to provide eligibility for access to our data and documents. The access is not limited to researchers and experts working in places other than universities or research centers can also have access to our documents.

Under which criteria data/document could be used

Since the immunogenicity is evaluated in phase 1, there is no need to perform analysis other than items mentioned in proposal. Both Chamran Hospital and Celltech Company must be referenced in case of any use of our documents and data.

From where data/document is obtainable

Contact documentation section of CellTech Pharmed company via m.ziraksaz@outlook.com or Dr. Mahdavi Health Research Centre via mahdavi.ag@gmail.com

What processes are involved for a request to access data/document

The applicants must provide us with documents indicative of their activity in cell therapy domain and prove their need to have access to the documents related to this study.

Comments