

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Safety of Intranasal Spray Containing the Conditioned Medium of Mesenchymal Stem Cells Derived from Umbilical Cord Wharton's jelly in Alzheimer's Disease (Mild to Moderate) in phase 1 of a clinical trial

Protocol summary

2024-02-19, 1402/11/30

Study aim

An evaluation of the safety of IN of CM Derived from Umbilical Cord WJMSCs in Alzheimer's patients

Design

Clinical trial with intervention groups (before and after), without blinding and randomization, Prism software for data analysis, phase 1 on 9 patients

Settings and conduct

-Interventional, Pre-Post, Within-group studies. -Patients referring to the Brain and Cognition Clinic (Firouzgar Hospital IUMS) & written consent from Sampling: Random& Convenience -Isolation of CM Steps: phase 1,2 and 3 Until complications in a dose more than 2.3 or 1.6, (toxic dose) the lower dose (safe dose & tolerated).

Participants/Inclusion and exclusion criteria

9 patients with mild to moderate AD dementia (Phase 1)
Inclusion: MMSE Score:18-24 Males and Females (60 to 85 Years) Exclusion: Cancer & Mental disorders

Intervention groups

3 patients in each group (n=3) Group 1: 1cc CM Group 2: 2cc CM Group 3: 3cc CM

Main outcome variables

Primary: Adverse Events & Changes in Biomarkers
Secondary: Cognitive Function Events (IADL & MoCA)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240131060870N1**
Registration date: **2024-02-19, 1402/11/30**
Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

Registrant information

Name

Setareh Akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-15, 1403/01/27

Expected recruitment end date

2025-04-16, 1404/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety of Intranasal Spray Containing the Conditioned Medium of Mesenchymal Stem Cells Derived from Umbilical Cord Wharton's jelly in Alzheimer's Disease (Mild to Moderate) in phase 1 of a clinical trial

Public title

Investigating the Effect of Intranasal Spray Containing Conditioned Medium from Umbilical Cord in Alzheimer's Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who have brain structural changes based on MRI and doctor's diagnosis, which confirms their Alzheimer's dementia. Gender and Age: men and women between 60 and 85 Y. Diagnosis of Mild to Moderate Alzheimer's dementia at least 6 months before the start of the study. MMSE (Mini-Mental State Examination) Score: 10 and 24 at the time of starting the study

Exclusion criteria:
Cancer patients who have been diagnosed in the last 5 years. Patients who cannot undergo MRI due to their condition. People with mental disorders Have diseases such as vitamin B12 deficiency, diabetes, hypo/hyperthyroidism, and hepatitis. History of cell therapy in the last 6 months. Subjects who have participated in another clinical study within 3 months before the start of this study. History of brain neoplasm.

Age
From **60 years** old to **85 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **9**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Convenience Sampling

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Ethics Committee in Biomedical Research, Ethics in Research Working Group, Research and Technology Vice President, Central Headquarters Building, Iran University of Medical Sciences, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2024-01-06, 1402/10/16

Ethics committee reference number
IR.IUMS.REC.1402.885

Health conditions studied

1

Description of health condition studied
Mild to moderate phase ,Alzheimer's patients, Alzheimer Disease, AD, Dementia

ICD-10 code
G30.1

ICD-10 code description
Diseases, Nervous System, Degenerative, Alzheimer's Disease, Late-onset, After the age of 65, AD, Dementia, Neurodegenerative, Central nervous system, CNS

Primary outcomes

1

Description
Fever

Timepoint
Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement
Thermometer

2

Description
Headache

Timepoint
Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement
Visual Analogue Scale (VAS)

3

Description
Dizziness, Nausea, and Vomiting

Timepoint
Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement
Dizziness Questionnaire: is a 25-item self-report questionnaire that quantifies the impact of dizziness on daily life by measuring self-perceived handicap. Item scores are summed. There is a maximum score of 100 (28 points for physical, 36 points for emotional and 36 points for functional) and a minimum score of 0

4

Description
Pro-inflammatory cytokines: IL-1β, TNF-α and IL-6

Timepoint

Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement

Human interleukin ELISA kit: designed for quantitative measurement of $\beta 1$, IL-6 and TNF alpha in serum, plasma, cerebrospinal fluid and cell culture supernatant samples. This kit is designed and produced using monoclonal antibodies against human interleukins. Therefore, it is not used in measuring similar animal cases.

5

Description

Growth Factors:GF:TGF- β and BDNF

Timepoint

Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement

ELISA kit Human TGF-B and BDNF: designed to detect TGF- β and BDNF in tissue samples, serum, plasma, cerebrospinal fluid and human cell culture supernatant.

6

Description

Protein Amyloid beta (A β)

Timepoint

Days 0, 1,2,3,4 and 2 weeks after CM (Conditioned Medium) therapy

Method of measurement

Blood Sample: Measurement of beta-amyloid plasma level by blood test

Secondary outcomes

1

Description

The instrumental Activities of Daily Living Scale (IADL) is used to assess a patient's independent living skills and measures.

Timepoint

0 ,2 week,1 and 3 month after CM therapy

Method of measurement

IADL Paper Questionnaire: which has 18 points.

2

Description

Montreal Cognitive Assessment Test (MOCA): was designed as a rapid screening tool for "mild cognitive impairment" and "Alzheimer's disease".

Timepoint

0 ,2 week,1 and 3 month after CM therapy

Method of measurement

MOCA Paper Questionnaire: It is used to measure different levels of memory and the person must have at least 6 classes of literacy.

3

Description

Questionnaire ADL (Activities of Daily Living Scale) is a tool designed to measure the level of independence in ADLs in clinical outpatient populations

Timepoint

0 ,2 week,1 and 3 month after CM therapy

Method of measurement

Questionnaire ADL is paper-based and has 14 points.

Intervention groups

1

Description

Intervention group:: First, conditioned media solution or conditioned medium derived from mesenchymal stem cells from Wharton's jelly umbilical cord, 1 cc as an intranasal spray, twice a day (every 12 hours), for 3 consecutive days, produced in the hospital Motahari, Iran University of Medical Sciences

Category

Treatment - Drugs

2

Description

Intervention group: Second, CM, 2 cc as an intranasal spray, twice a day (every 12 hours), for 3 consecutive days,

Category

Treatment - Drugs

3

Description

Intervention group: Third, CM, 3 cc as an intranasal spray, twice a day (every 12 hours), for 3 consecutive days,

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Cognition Clinic (Firoozgar Hospital IUMS)

Full name of responsible person

Mostafa Almasi-Dooghaee

Street address

Brain and Cognitive Clinic, Firoozgar Hospital, Beh Afrin Street, Karim Khan Zand Street,Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Reza Falak

Street address
5th floor of the central headquarters, Research and
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Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology, Iran University of
Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Naser Amini

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Neuroscience

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

When the data will become available and for how long

To whom data/document is available

Under which criteria data/document could be used

From where data/document is obtainable

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

Comments