Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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
2024-02-19, 1402/11/30

Registrant information

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Setareh Akbari

Name of organization / entity

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Iran (Islamic Republic of)

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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 β1, 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 (Aβ)
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
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Sponsors / Funding sources

1

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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

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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
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