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Comparison of the effect of pure fat injection vs injection of enriched fat with stem cells in repairing age-related changes on the face

Submission date
29/04/2022

Recruitment status
No longer recruiting

Registration date
19/07/2022

Overall study status
Completed

Last Edited
31/08/2022

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The use of autologous fat graft (the patient's own fat) as a filler or transplantation material is a well-known but controversial way to augment soft tissues and treat a wide range of acute and chronic soft tissue deficiencies and diseases and even has been used to correct aging changes. Recently, the role of stem cells in adipose (fat) tissue has been taken into consideration, because these cells do not have any immunological risks and may lead to the improvement of adipose tissue repair and reduce the absorption of this tissue, increasing its survival and patient satisfaction. The aim of this study is to determine the effect of stem cell enriched fat injections in the short and long-term results of fat transplantation for correction of facial aging changes.

Who can participate?
Women aged 20-60 years old asking for treatment for facial aging changes and referred to a plastic surgery clinic in Mashhad during the years of 2014 to 2015

What does the study involve?
Fat injection and/or stem cell enriched fat transplantation are performed, and examinations and medical photography are performed before and after the procedure and at intervals of 6, 12, and 18 months later. The photographs of each patient are evaluated by a panel of referees consisting of two female general practitioners, a plastic surgeon unrelated to the patient's treatment process, and an experienced hairdresser using an investigator-generated checklist. It should be noted that the photographs are anonymous, the characteristics of the applicants and the type of injection are coded and the judges are unaware of the sort of treatment. The referees report the final results as ineffective, poor, good, very good, and excellent (1 to 5, respectively) and the photographs and the current condition of the patients are evaluated by themselves and assigned a score of 1 to 5 to the outcome of the fat grafting. It is important to note that the referee's panel and patients complete a separate checklist for scoring each stage (6, 12 and 18 months after injection) so they are unaware of their previous scores. Finally, the results of patients in groups 1 and 2 are compared with each other, and in addition, the age of

the applicants is also considered to compare the outcome of fat injection enriched with stem cells of the individual adipose tissue (group 2) with the usual method of injection of pure fat (group 1) on repairing the changes caused by aging on the face.

What are the possible benefits and risks of participating?
Autologous fat injection with the individual's own fat is fully compatible with other living tissues of the body and therefore the safest choice for changing the volume of the face and at the same time brings a natural appearance to the patient. This process is non-carcinogenic and does not cause an immune response in the host and leaves the least scar at the recipient site. In addition, with a single fat aspiration, 1: 100 to 1: 1500 cells can be easily obtained, which is 50 times more than mesenchymal stem cells obtained from bone marrow. Common complications include edema (swelling), erythema (rash), itching, burning, bruising, and less common complications include hematoma (bruising), cellulite (dimpled skin), fibrosis (scarring), fatty cysts (lumps), and calcification (calcium buildup).

Where is the study run from?
Islamic Azad Medical University (Iran)

When is the study starting and how long is it expected to run for?
September 2013 to September 2016

Who is funding the study?
1. Islamic Mashhad Medical Sciences University (Iran)
2. Academic Center for Education, Culture and Research (ACECR) (Iran)

Who is the main contact?
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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
Comparison of the effect of pure autologous fat grafting with adipose tissue-derived stem cell-enriched autologous fat grafting on the restoration of age-related changes on the face

Study objectives
The effect of pure autologous fat grafting with adipose tissue-derived stem cells-enriched autologous fat grafting on repairing age-related changes 6 months after injection is different.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2018, Research Ethics Committee of Islamic Azad University, Islamic Azad Medicine School of Mashhad branch (Dr Shahin far Faculty of Medicine, Bazarcheh Sarab, Imam Khomeini 14, Mashad, Iran; ethics@mshdiau.ac.ir, ethics.mshdiau@gmail.com), ref: IR.IAU.MSHD.REC.1396.129

Study design
Two-centre interventional quasi-randomized double-blind trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Facial fat injection due to aging changes

Interventions
This quasi-randomized clinical trial study was performed on 72 women aged 20-60 years old who applied for fat transplantation referred to the plastic surgery clinic during 2015-16 in Mashhad.

The eligible applicants after examination by a plastic surgeon, at the discretion of the physician in terms of the possibility of performing the fat injection process, if they meet the inclusion criteria and do not have exclusion criteria, enter the study.

Then, the method of injection of pure fat and the method of injection of fat enriched with adipose tissue-derived stem cells (ADSCs) are explained to the applicants and according to their demand and desire, they are placed in one of the two study and control groups.

Group 1 (control group): After the initial examination and obtaining the patient's consent and signature the consent, the areas required for fat grafting on the face are marked, and pre-injection photographs are taken. The required fat is then prepared as follows:

First, the site of fat tissue removal (donor site) is marked on the thigh, flank, or abdomen, and then Tumescent solution (containing epinephrine, lactate ringer, lidocaine, and bicarbonate) to the required amount (usually 200-300 cc) was injected into the donor site. After 20 minutes, the sufficient autologous fat graft was prepared by 10 cc syringe and Coleman aspiration cannula. The syringes were placed vertically to separate the liquid from the aspirated adipose tissue due to gravity. The fat was transferred to 2 cc syringes (Leur lock) and injected in suitable and predetermined sites by Coleman injection cannula style 1. At the end, the postoperative care booklet and medication instructions were delivered to the participants.

Follow-up: Applicants are referred on the third to fifth day to the clinic for initial examination, and then at intervals of 6, 12, and 18 months examination and photography are performed. Any patients who wishes can repeat the fat injection to achieve a better result, but the minimum interval for re-injection will be 3 months.

Group 2 (study group or case): After obtaining the patient's consent and written signature the consent for injection of enriched fat with the autologous adipose tissue stem cells (ADSCs) and initial examination, the areas required to receive fat graft on the face are identified and marked, and pre-injection photographs are taken. Then, similar to group 1, fat is prepared from the donor site, but the required volume is doubled or more aspirated to separate the stem cells from the excess fat.

This fat is sent to Mashhad University Jahad Cytology Research Laboratory for enrichment, where the required volume for injection is separated and the rest of the fat enters the process of stem cell isolation. After separating the cells and counting their number, the cells are added to the remaining adipose tissue (enrichment), the samples are subjected to a cell viability test, and the prepared ADSCs-enriched autologous fat graft was sent to a private clinic. The total operation takes about 3 hours. The total operation takes about 3 hours. The ADSCs-enriched autologous fat graft was injected in the same way as group 1.

Follow-up: similar to group 1 examination and photography are performed at 6, 12, and 18 months after the injection. After 18 months, the profiles of the applicants of groups 1 and 2 undergo a detailed review. The photographs of each patient are then evaluated by a panel of referees consisting of two female general practitioners, a plastic surgeon unrelated to the patient's treatment process, and an experienced hairdresser. It should be noted that postoperative photographs were anonymous, the characteristics of the applicants and the type of injection were coded and the judges were unaware of the sort of treatment. The referees reported the final results as ineffective, poor, good, very good, and excellent (1 to 5, respectively) in addition the photographs and the current condition of the patients are evaluated by themselves and assigned a score of 1 to 5 to the outcome of the fat grafting. It is important to note that the referee's panel and patients complete a separate checklist for scoring each stage (6 months, 12 months, and 18 months after injection) so they are unaware of their previous scores. Finally, the results of patients in groups 1 and 2 are compared with each other, and in addition, the age of the applicants is also considered to determine whether the therapeutic outcome of fat-enriched fat injection with stem cells of the individual adipose tissue (group 2) with the usual method of injection of pure fat (group 1) on repairing the changes caused by aging in the face is different.

Intervention Type
Procedure/Surgery

Primary outcome measure
Difference between the two groups in terms of the effect of pure autologous fat grafting vs adipose tissue-derived stem cell-enriched autologous fat grafting on age-related changes on the face, measured using the investigator-generated checklist, medical photography, and a panel of referees consisting of two female general practitioners, a plastic surgeon unrelated to the patient's treatment process and an experienced hairdresser, evaluated before and after the procedure and at intervals of 6, 12, and 18 months.

Secondary outcome measures
Age and patient demographic information evaluated using a demographic questionnaire at baseline

Overall study start date
23/09/2013

Completion date
21/09/2016

Eligibility

Key inclusion criteria
1. Women aged 20 to 60 years
2. Body mass index (BMI) 18.5 to 25 kg/m²
3. Symmetrical face

Participant type(s)
Healthy volunteer

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
242

Total final enrolment
72

Key exclusion criteria
1. Systemic diseases (such as diabetes and hypertension)
2. Taking immunosuppressive drugs (such as corticosteroids), anticoagulants (such as aspirin), and non-steroidal anti-inflammatory drugs (such as ibuprofen)
3. History of allergy to anesthetics
4. History of psychiatric disorders (such as body dysmorphic disorder and anorexia nervosa, etc)
5. Weight gain or weight loss diet

Date of first enrolment
21/03/2014

Date of final enrolment
21/03/2015

Locations

Countries of recruitment
Iran

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University/education

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Funder(s)

Funder type
University/education

Funder Name
Mashhad University of Medical Sciences

Alternative Name(s)
MUMS

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Iran

Funder Name
Academic Center for Education, Culture and Research

Alternative Name(s)

ACECR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Iran

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
19/07/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Published as a supplement to the results publication