

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of umbilical cord Wharton's jelly on mother's melasma

Protocol summary

Study aim

Evaluation of effect of Wharton's umbilical cord jelly on mother's melasma

Design

In this research, 50 mothers with melasma referring to Anadan and Khoramshahr hospital were chosen purposefully and were randomly divided into two groups of control and intervention. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

Mothers with melasma referring to Abadan and Khoramshahr hospitals will be registered for this study. Patient and investigators evaluating melasma will be blinded to the type of therapy

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Mothers with melasma
Exclusion Criteria: Exposure to the direct sun light, Systemic steroid therapy, Suffering from another skin disease such as rash and acne, Suffering from systemic disease with dermatological signs such as Hepatitis C and Lupus Erythematosus

Intervention groups

Treatment group: Mother with melasma treated with Wharton's Jelly
Control group: Mother with melasma treated with the base of cream

Main outcome variables

Melasma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180116038386N1**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **retrospective**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Maryam Adelipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 5326 7800

Email address

m.adelipour@abadanums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of umbilical cord Wharton's jelly on mother's melasma

Public title

Effect of umbilical cord Wharton's jelly in treatment of melasma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mother with melasma

Exclusion criteria:

Another skin disease such as rash, acne, Systemic

disease with dermatological signs such as Hepatitis C Virus , Lupus Erythematosus, Systemic steroid therapy Exposure to direct sunlight

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization will be simple. Unit of randomization will be individual. Tools of randomization will be random number table. Person randomising the patient does not know what the next treatment allocation will be.

Blinding (investigator's opinion)

Double blinded

Blinding description

For elimination of the possibility of any probable bias due to the knowledge of patients and investigators about the type of treatment we will perform a double blind study. The patients and investigators were blinded to treatment type (Wharton's Jelly or base of cream). placebo (base of cream) will be similar to Wharton jelly in figure, color and volume. Wharton's Jelly or base of cream is used on face of patients topically by a educated person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Abadan University of Medical Science

Street address

Airport Blvd

City

Abadan

Province

Khuzestan

Postal code

6313833177

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.ABADANUMS.REC.1396.245

Health conditions studied

1

Description of health condition studied

Melasma

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Melasma

Timepoint

Before intervention and 6 weeks after intervention

Method of measurement

Melasma area severity index (MASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A part of umbilical cord (10 cm) will be cut immediately after parturition and will be washed in sterile plate using sterile normal saline. Warthon Jelly will be extracted using a razor blade. Extracted warthon jelly will be used on hyperpigmentation area of mothers face topically. This intervention will be single dose.

Category

Treatment - Other

2

Description

Control group: Base of cream. single dose

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Hanan Sorkheh

Street address

Ahmad Abad

City

Abadan

Province

Khuzestan

Postal code

6316648371

Phone

+98 61 5332 9400

Email

M.Adelipour@Abadanums.ac.ir

2**Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Horia Bahrami

Street address

Shohadaye Sazeman Ab Boulevard

City

Khoramshahr

Province

Khouzestan

Postal code

6418733891

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+98 61 5354 4800

Email

M.Adelipour@Abadanums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Abadan University of Medical Sciences

Full name of responsible person

Dr. Nouri

Street address

Abadan Faculty of Medical Science, Ayatollah Jami
Ariport, Airport sq, Abadan, Iran

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Abadan University of Medical Sciences

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**

Abadan University of Medical Sciences

Full name of responsible person

Maryam Adelipour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All of data will be shared.

When the data will become available and for how long

One month after publishing data

To whom data/document is available

Researcher in each field

Under which criteria data/document could be used

Use in therapy

From where data/document is obtainable

Authors of article

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

Almost one month

Comments