

# 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

**Country of origin****Type of organization providing the funding**

Academic

**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

**Phone**

+98 61 5354 4800

**Email**

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**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**City**

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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

**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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## Person responsible for updating data

### Contact

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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**