

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of treatment with nicotine patches versus support behavior in smoking cessation in pregnant women

#### Protocol summary

##### Study aim

abstinence from the date of smoking cessation until delivery

##### Design

Two arm parallel group randomized trial, double - blind , placebo- controlled to assess nicotine - replacement patches for prolonged abstinence from smoking during pregnancy

##### Settings and conduct

Midwives researches study enrollment of women who agreed with the quit in two weeks. Subjects randomly received 4 weeks of patches of skin (containing 15 mg of nicotine every 16 hours) in place of placebo for delivery to mothers and one month after the start of the study, salivary cotinin test was taken from mothers who said they did not smoke. When less than 8 ppm, nicotine patches were given to moms for another 4 weeks. The patches of the placebo group are very similar to nicotine patches.

##### Participants/Inclusion and exclusion criteria

inclusion criteria : women who agreed to set a quit date , 16 to 50 years of age , 12 to 24 weeks of gestation , smoked 10 or more cigarettes daily before pregnancy, currently smoked 5 or more cigarettes daily exclusion criteria : known major fetal abnormalities , inability to provide informed consent , chemical or alcohol dependence , chronic generalized skin disorders

##### Intervention groups

pregnancies of 12 -24 to weeks gestation

##### Main outcome variables

abstinence from the date of smoking cessation until delivery - out comes for the fetus and baby: miscarriage , stillbirth , neonatal death , congenital abnormality , neonatal convulsion , birth weight

#### General information

##### Reason for update

##### Acronym

NRT

##### IRCT registration information

IRCT registration number: **IRCT20181209041904N1**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **prospective**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

##### Registration date

2018-12-21, 1397/09/30

##### Registrant information

###### Name

zohre gozidehkar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3258 3449

###### Email address

zohre.gozidehkar@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-26, 1398/01/06

##### Expected recruitment end date

2022-03-26, 1401/01/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effectiveness of treatment with nicotine patches versus support behavior in smoking cessation in pregnant women

**Public title**

Nicotine-Replacement Therapy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of 16-50 years 12-24 weeks of pregnancy Smoking is 10 or more cigarettes a day before pregnancy Daily smoking of 5 yarns during the current pregnancy

**Exclusion criteria:**

Maternal mothers who have been diagnosed with ultrasound diagnosis of fetal abnormalities. Pregnant women who are allergic to chemicals or alcohol Pregnant mothers with generalized skin diseases Pregnancy mothers who are allergic to nicotine patches

**Age**

From **16 years** old to **50 years** old

**Gender**

Female

**Phase**

0

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **1050**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization Individual randomization unit

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and midwives have been blinded to study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethnics committee of zahedan university of medical sciences

**Street address**

dr hesabi aveniu

**City**

zhedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9769144155

**Approval date**

2018-11-12, 1397/08/21

**Ethics committee reference number**

354554

**Health conditions studied****1****Description of health condition studied**

Addiction in pregnancy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

self-reported abstinence from smoking between the quit date and child-birth

**Timepoint**

Before the intervention, 4 weeks after the intervention, 8 weeks after the intervention, the delivery time

**Method of measurement**

Perform salivary catechin test and CO respiration test

**Secondary outcomes****1****Description**

Consequences of birth include: abortion - stillbirth - birth weight - congenital anomaly

**Timepoint**

Delivery time

**Method of measurement**

Self-report pregnant mothers and perform salivary cotinine test

**Intervention groups****1****Description**

Intervention group: Pregnant women 12-24 weeks of pregnancy

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Nashat Addiction Treatment Center

**Full name of responsible person**

zohre gozidehkar

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zahedan University of Medical Sciences  
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#### Grant name

**Grant code / Reference number**  
256542

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

Yes

#### Title of funding source

Zahedan University of Medical Sciences

#### Proportion provided by this source

80

#### 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**  
Zahedan University of Medical Sciences  
**Full name of responsible person**  
zohre gozidehkar  
**Position**  
student  
**Latest degree**

Bachelor  
**Other areas of specialty/work**  
Epidemiology  
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## Person responsible for scientific inquiries

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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**

No - There is not a plan to make this available

**Analytic Code**

Yes - There is 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**

All data is unobtrusive when unrecognizable

**When the data will become available and for how long**

Start one-year access period after printing results

**To whom data/document is available**

Researcher of medical universities of Iran

**Under which criteria data/document could be used**

Use of methodology and study results is free

**From where data/document is obtainable**

Requests for documentation via e-mail

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

After receiving the email, the response will be given one month later

**Comments**