Study of local effect of olive and Saj (Teak) Cream on the intensity of nulipara women's striae gravidarum

Protocol summary

Summary
Background & Purpose: Striae gravidarum is observed among 50-90 percent of pregnant women and creates aesthetic concern among them. No final therapy has been determined for this because of its unknown etiology. The aim of this study is to determine the effects of olive oil and Saj cream on the severity of striae gravidarum. Methodology: This study was conducted as a randomised clinical trial with control group on 150 nulliparous women, 20-30 years, in their 18th to 20th weeks of gestation and with body mass indices between 18.5 and 25 visiting the urban health & treatment centers in Tehran. The two intervention groups consisted of women who took either olive oil or cream saj on the skin of abdominal wall twice a day until the end of the study term. The control group did not receive any cream or oil. Personal specification questionnaires were completed for each subject via interviews early in the study and through researcher's observation in later phases. Exclusion criteria: multiple pregnancies; polyhydraminos; skin disorders, administration of corticosteroids, application of other ointments on abdominal area, unwilling to continue the interventions at a three time a week rate. Subjects were followed weekly up until their 37th to 40th weeks of pregnancy. The severity of the striae was measured with DAVEY tool and data was analyzed using descriptive statistics and chi-square test.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT138807282172N2
Registration date: 2010-12-29, 1389/10/08
Registration timing: retrospective

Last update: 0
Registration date: 2010-12-29, 1389/10/08

Registrant information
Name: Simin Taavoni
Name of organization / entity: Iran University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Deputy of research of Medical Science University of Iran and the Sepidroo Company, manufacturer of beauty and health products

Expected recruitment start date: 2009-07-27, 1388/05/05
Expected recruitment end date: 2010-04-25, 1389/02/05
Actual recruitment start date: empty
Actual recruitment end date: empty
Trial completion date: empty

Scientific title
Study of local effect of olive and Saj (Teak) Cream on the intensity of nulipara women's striae gravidarum

Public title
Study of local effect of olive and Saj (Teak) Cream on the intensity of nulipara women's striae gravidarum

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Healthy mothers between 18-20 weeks, body mass index of 18.5-25 Exclusion criteria: More than one baby, Polyhydraminos, Skin disease, usage of corticosteroid medication, Macrosome babies (more than 4 kilogram), Babies under 2500gr, Premature childbirth, usage of other creams in the abdominal, Unwilling to participate in the study, usage of the oils less than three times in a week

Age
From **20 years** old to **30 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
No information

**Sample size**  
Target sample size: **360**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  

**Secondary Ids**
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**  
Nursing and midwifery colleg in Iran university of medical Sciences

**Street address**  
Rashid YasamiST. Valiasr AVE

**City**  
Tehran

**Postal code**  
4798/19395

**Approval date**  
2009-03-16, 1387/12/26

**Ethics committee reference number**  
1464883

**Health conditions studied**

1

**Description of health condition studied**  
Striae Gravidarum

**ICD-10 code**  
L90.6

**ICD-10 code description**  
Striae atrophica

**Primary outcomes**

1

**Description**  
Severity of Striae Gravidarum

**Timepoint**  
Follow up were done by phone every week

**Method of measurement**  
Observation and recording of Striae Gavidarum

**Secondary outcomes**
empty

**Intervention groups**

1

**Description**  
The first intervention group were taught to apply olive oil topically onto their abdominal skin; twice a day without massaging

**Category**  
Treatment - Drugs

2

**Description**  
The control group were advised not to use any oil or ointment on their abdominal area.

**Category**  
Treatment - Drugs

3

**Description**  
The second intervention group were taught to apply cream saj topically onto their abdominal skin; twice a day without massaging

**Category**  
Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**  
West Health Centre

**Full name of responsible person**  
Haleh Ahmadiyn

**Street address**  
Enter of Dastgheib St, Ostad Moein Ave

**City**  
Tehran

2

**Recruitment center**

**Name of recruitment center**  
Lolagar Hospital

**Full name of responsible person**  
Fariba Headari Kohan

**Street address**  
Khosh Ave at the Dampezeshki and Azarbaijan crossings

**City**  

Recruitment center
Name of recruitment center
Akbar Abadi Medical Education & Treatment Center
Full name of responsible person
Maryam Kashaniyan
Street address
Corner of Madar St, Bagh Ferdows station, Molavi Ave
City
Tehran

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Dr. Saeid Abass Motevalain, Dr. Mazyar Moradie Lakea
Street address
Iran University of Medical Sciences, Crossroads of Shahid Hemmat & Shahid Chamran Express Ways
City
Tehran
Grant name
Grant code / Reference number
773
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Iran University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
Nursing and Midwifery Faculty, Iran University of Medical Sciences
Full name of responsible person
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Other areas of specialty/work
City
Tehran

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty