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# Prevention of stretch marks in pregnancy: a pilot trial

**Submission date**
03/07/2017

**Recruitment status**
Stopped

**Registration date**
14/07/2017

**Overall study status**
Stopped

**Last Edited**
14/02/2020

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

Background and study aims
Stretch marks affect many women during pregnancy, particularly in the third trimester. They affect between 50% and 90% of women and are most commonly found during a first pregnancy. They appear as red lines or streaks that fade slowly after the pregnancy to leave pale lines on the skin. Areas of the body frequently affected are the abdomen, breasts, thighs and buttocks. They are reported as affecting women's perception of themselves. Further their prevention is important to women, and women frequently ask how they can be prevented during pregnancy. There is a lack of research on the prevention of stretch marks and there is a need for large studies to investigate how effective some of the products used by women are. The aim of this study is to examine the feasibility of undertaking a larger trial to evaluate the effects of a moisturising oil on the prevention and reduction of stretch marks in pregnancy, which has not being done to date.

Who can participate?
Women aged 18 and older who are around 12-16 weeks pregnant (with one baby).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are asked to apply around 2 ml (about two pumps) of the plain moisturising oil daily to their abdomen after showering, from when they join the study until 38-41 weeks of pregnancy. Those in the second group are asked not to apply any treatment or skin product to their abdomen during pregnancy. Participants are asked to keep diaries of the application as appropriate. Participants receive two weekly text messages to remind them of their participation. Those in the first group are asked to bring their empty oil bottles to an interview at 38-41 weeks of pregnancy. Participants undergo health questions and are measured for weight at the start of the study and at the final assessment between 38-41 weeks of pregnancy.

What are the possible benefits and risks of participating?
There are no direct benefits or risks of participating.

Where is the study run from?
University Hospital Galway (Ireland)

When is the study starting and how long is it expected to run for?
September 2015 to April 2019

Who is funding the study?
Investigator imitated and funded (Ireland)

Who is the main contact?
Ms Miriam Brennan

# Contact information

### Type(s)
Scientific

### Contact name
Ms Miriam Brennan

### Contact details
School of Nursing & Midwifery
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# Additional identifiers

# Study information

### Scientific Title
Prevention of striae gravidarum: a pilot trial

### Study objectives
The aim of the study is to evaluate the feasibility of conducting a randomised controlled trial to evaluate the effectiveness of a moisturising oil (commercially available moisturising oil) compared to no treatment for the prevention and reduction in severity of striae gravidarum.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Galway Clinical Research Ethics Committee for University College Hospital Galway, 08/06/2017, ref: C.A.1770-Prevention of Striae Gravidarum: A Pilot Trial

### Study design
Single-centre two arm unblinded pragmatic parallel randomised trial

### Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Striae gravidarum

## Interventions
Participants are randomly allocated to either the intervention or the control group using a 1:1 randomisation ratio using random block sizes.

Intervention group: Participants receive a moisturising oil (commercially available moisturising oil). They are asked to apply approximately 2 ml per day (two pumps of oil) to their abdominal skin over 26 weeks of their pregnancy (i.e. between 12-14 weeks up to approximately 38 weeks gestation) (updated 16/07/2018: between 12-16 weeks up to approximately 38 weeks gestation)

Control group: Participants do not receive any treatment.

Participants are asked to keep diaries of the application as appropriate. Participants receive two weekly text messages to remind them of their participation. Those in the intervention group are asked to bring their empty oil bottles to an interview at 38-41 weeks of pregnancy.

Participants are followed up at 38-41 weeks of gestation to see if the study is feasible and to assess their level of striae gravidarum. They undertake assessment interviews at this time and are measured for weight.

## Intervention Type
Other

## Primary outcome(s)
1. Number and proportion of women who are recruited, enrolled, complete the study and adhere to the intervention and control guidelines is measured using trial register form and outcomes assessment form, at enrolment (12-14 weeks gestation; updated 16/07/2018: 12-16 weeks gestation) and outcomes assessment interview (38-41 weeks gestation)
2. Percentage of potentially eligible women who are recruited/enrolled to the study is measured using trial register form at enrolment
3. Challenges with the randomisation process is reported based on the researcher’s notes at the enrolment/randomisation stage
4. Number and proportion of women who withdraw, drop out or deviate from the protocol guideline is measured using the outcome assessment form at 38-41 weeks gestation
5. Reasons for non-recruitment, non adherence, or attrition is measured using the Trial register form and Outcome assessment form at enrolment (12-14 weeks gestation; updated 16/07/2018: 12-16 weeks gestation) and outcomes assessment interview (38-41 weeks gestation)
6. Women's rating of the tolerability/acceptability and effectiveness of the intervention is measured using a rating scale at 38-41 weeks of pregnancy
7. Completeness of data collection for outcomes is measured using % of missing data at outcomes assessment (38-41 weeks gestation)
8. Challenges with data analysis is reported based on the researchers study notes at the analyses stage
9. Number and proportion of women developing striae gravidarum in the intervention and control group is measured using the Davey instrument (1972) at 38-41 weeks
10. Number and proportion of women developing mild, moderate or severe striae gravidarum is

measured using Classification system of mild, moderate or severe at 38-41 weeks
11. Women's perception of the severity of striae gravidarum is measured using a grading system of none, mild, moderate or severe at 38-41 weeks

### Key secondary outcome(s)
Infant's birth gestation and infant weight is measured using number of weeks at birth & Kg recorded in the mother’s notes at time of birth.

### Completion date
30/04/2019

### Reason abandoned (if study stopped)
Participant recruitment issue

## Eligibility

### Key inclusion criteria
1. Primigravid women
2. Singleton pregnancy
3. 12-14 weeks gestation at time of recruitment; updated 13/07/2018: 12-16 weeks gestation at time of recruitment
4. Absence of abdominal striae
5. Aged 18 or over at recruitment
6. English speaking women

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Female

### Key exclusion criteria
1. Multigravid women (due to risk of having striae from an earlier pregnancy)
2. Women taking corticosteroids for any reason (due to their association with skin striae)
3. Multiple pregnancy (due to increased maternal weight gain and skin stretching)
4. Women with a known hypersensitivity to agents in baby oil (due to risk of allergic reaction)
5. Women with known disorders or illnesses that may be associated with striae, e.g., Marfan syndrome, Cushing syndrome
6. Women who decline to discontinue other creams or lotions
7. Women who are unable to give informed consent

**Date of first enrolment**
17/07/2017

**Date of final enrolment**
31/08/2018

# Locations

**Countries of recruitment**
Ireland

**Study participating centre**
**University Hospital Galway**
Maternity Unit
Newcastle Road
Galway
Ireland
H91 YR71

# Sponsor information

**Organisation**
National University of Ireland Galway

**ROR**
https://ror.org/03bea9k73

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study are/will be available upon request from Miriam Brennan (Miriam.brennan@nuigalway.ie)

## IPD sharing plan summary

Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 12/10/2018 | | Yes | No |
| Other publications | qualitative study of the factors influencing recruitment | 12/02/2020 | 14/02/2020 | Yes | No |