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Safety and efficacy of a cream on the wound healing and scar of cesarean section

Submission date
08/05/2024

Recruitment status
No longer recruiting

Registration date
10/05/2024

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
One of the most popular surgical procedures is the cesarean section (CS), and one of the most prevalent side effects of this procedure is wound and scar issues. The aim of this prospective, short-term, placebo-controlled study is to evaluate the safety and effectiveness of a silicone-based medical device (Lecoxen cream, Ekuberg Pharma, Italy) in healing wounds and scars derived from cesarean sections in nulliparous women. Methods:

Who can participate?
Women, ranging in age from 18 to 45 years, who underwent CS

What does the study involve?
Participants are divided in two groups of treatment (Lecoxen cream or Vaseline). The quality of scar will be examined using the Vancouver scar scale after 28 days, while wound healing will be evaluated using the redness, edema, ecchymosis, discharge, and approximation (REEDA) scale on the 14th day following CS.

What are the possible benefits and risks of participating?
Possible benefits: reduciton of healing time of wound and amelioration of scar tissue
Possible risk: allergies to any of the ingredients contained in the proposed treatment

Where is the study run from?
Department of Obstetrics and Gynecology “Veris delli Ponti Hospital” (Italy)

When is the study starting and how long is it expected to run for?
June 2023 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Andrea Tinelli, andreatinelli@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
75839/2023

Study information

Scientific Title
Safety and efficacy of Lecoxen cream on the wound healing and scar of cesarean section: a prospective observational clinical trial

Study objectives

Lecoxen cream is more effective than pure Vaseline in reducing time of healing of wound resulting from cesarean section and improve quality of resulting scar.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 06/06/2023, Ethical committee of Lecce (Via Miglietta 5, Lecce, 73100, Italy; +39 836 420273; cometico@asl.lecce.it), ref: 75839/2023

Primary study design
Interventional

Study design
Single center interventional randomized controlled trial

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Treatment of wound derived after cesarean section

Interventions
All pregnant women submitted to a Pfannenstiel skin incision will be included in the study. After surgery, skin will be closured by agrafes (Agrafes Appose, Medtronic Italy, Milano, Italy) and will be divided into two 71 groups: 37 mothers were allocated to the treatment group with Lecoxen cream, 37 to the placebo group treated with 72 Vaseline (Vaseline F.U., Marco Viti, Italy). Participants were assigned in a 1:1 ratio with sequential assignment, depending on time and date of enrolment.
After the stitches' removal, normally on the seventh post-operative day, patients will be instructed to apply respective treatments from the first day to the twenty-eighth day, once a day. Patients will be asked not to use any other medicament for wound healing.
A board-certified gynecologist, all doctors working in the department where the study will be performed, will supervised the screening, the enrollment of study participants from a panel of candidates, and will follow the patients during the study.
The state of wound healing will be evaluated at baseline and after 14 days (T1) of the treatment using Redness, Edema, Ecchymosis, Discharge, and Approximation (REEDA) scale. The degree of quality of the resulting scar will be finally evaluated after 28 days (T2), using Vancouver Scar Scale (VSS).

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lecoxen cream

Primary outcome(s)

1. The quality of scar was examined using the VSS scale at baseline and after 28 days
2. The wound healing was evaluated using REEDA scale at baseline and after 14 days

Key secondary outcome(s)
Adverse events measured using patient records up to the end of the study

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Healthy women aged 18 - 45 years scheduled for CS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
74

Key exclusion criteria
1. Smoking
2. At risk for premature birth
3. Obesity
4. Hypertension
5. Diabetes and infections
6. Use systemic and topical corticosteroids
7. Presence of previous surgical scarring near the incision site
8. Autoimmune diseases
9. Skin problems
10. Known hypersensitivity to at least one of the components of the formulation Lecoxen cream or Vaseline

Date of first enrolment
07/06/2023

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Italy

Study participating centre
Department of Gynecology and Obstetrics of the 'Veris Delli Ponti' Hospital
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Sponsor information

Organisation
Department of Obstetrics and Gynecology “Veris delli Ponti Hospital”

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 will be available upon request from Andrea Tinelli
andreatinelli@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		22/07/2024	27/01/2025	Yes	No