

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/05/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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: reduction 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

Study design

Single center interventional randomized controlled trial

Primary study design

Interventional

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 closed 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

Via Giuseppina Delli Ponti

Scorrano

Italy

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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