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Safety and efficacy of Hemopran protective endorectal cream in the management of pregnancy-related haemorrhoidal disease: a single-center study

Submission date
24/04/2026

Recruitment status
No longer recruiting

Registration date
07/05/2026

Overall study status
Completed

Last Edited
06/05/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Background and study aims
Haemorrhoidal disease (HD) is a common condition during pregnancy, often associated with discomfort, pain, and reduced quality of life. Treatment options are limited due to safety considerations in pregnant women. This study aimed to evaluate the effectiveness and tolerability of Hemopran® protective endorectal cream, a CE-marked medical device, in reducing the symptoms and signs of grade I–II haemorrhoidal disease in pregnant women.

Who can participate?
Pregnant women aged 18 years and over, in any trimester, with grade I or II haemorrhoidal disease

What does the study involve?
Participants received treatment with Hemopran® protective endorectal cream and were monitored over time. Outcomes were assessed using validated patient-reported outcome measures to evaluate symptom improvement and treatment tolerability.

What are the possible benefits and risks of participating?
Possible benefits include relief of haemorrhoidal symptoms and improved quality of life. Potential risks are minimal and may include local irritation or hypersensitivity reactions to the product components.

Where is the study run from?
Assisted Medical Reproduction (PMA) Center, Papardo Hospital, Messina (Italy)

When is the study starting and how long is it expected to run for?
February 2025 to December 2025

Who is funding the study?
Ekuberg Pharma S.r.l. (Italy)

Who is the main contact?
Dr Davide Carati, davide.carati@ekubergpharma.com

Contact information

Type(s)
Scientific, Principal investigator, Public

Contact name
Dr Davide Carati

ORCID ID
https://orcid.org/0000-0003-2360-3456

Contact details
Via Firenze
Sternatia
Italy
73010
+39 (0)3294513080
davide.carati@ekubergpharma.com

Additional identifiers

Study information

Scientific Title
Safety and efficacy of Hemopran protective endorectal cream in the management of pregnancy-related haemorrhoidal disease: a single-center study

Acronym
02-25

Study objectives
The primary outcome of the study was the reduction in the intensity and frequency of hemorrhoidal symptoms, as assessed by changes in individual Hemorrhoidal Disease Symptom Score (HDSS) items and in the total HDSS score between baseline and the end of treatment. Secondary outcomes included changes in health-related quality of life, evaluated through individual SHS-HD items and the overall SHS-HD score, as well as treatment tolerability and safety.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 11/02/2025, Local ethics committee of Messina (Via Consolare Valeria, 1, Messina, 98125, Italy; +39 (0)90 2217347; comitato.etico@polime.it), ref: 02-25

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science, Prevention, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Hemorrhoidal disease grade I–II in pregnant women

Interventions
All enrolled patients were treated with Hemopran® protective endorectal cream, a topical endorectal formulation indicated as a coadjuvant treatment for HD and anorectal mucosal irritation. Participants were instructed to apply the cream topically twice daily, preferably after personal hygiene and bowel movements, for a total treatment duration of 14 consecutive days. Treatment adherence and tolerability were assessed during follow-up.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hemopran® protective endorectal cream

Primary outcome(s)
1. The intensity and frequency of hemorrhoidal symptoms and changes in health-related quality of life measured using HDSS score and Short Health Scale for Hemorrhoidal Disease (SHS-HD) score at T0 (baseline) and T1 (after 14 days of treatment with the product)

Key secondary outcome(s))
1. Safety and tolerability measured using appearance of side effects at T0 (baseline) and T1 (after 14 days of treatment with the product)

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Women aged ≥18 years with a confirmed pregnancy in any trimester
2. Clinical diagnosis of non-thrombosed grade I or II hemorrhoidal disease (HD) according to the Goligher classification

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
99 years

Sex
Female

Total final enrolment
140

Key exclusion criteria
1. Advanced HD requiring surgical intervention (grade III or IV)
2. The presence of concomitant anorectal conditions such as anal fissures or perianal abscesses
3. Known hypersensitivity to any component of the study product
4. The use of topical or systemic anti-hemorrhoidal treatments within 14 days prior to enrollment

Date of first enrolment
11/02/2025

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Assisted Medical Reproduction (AMP) Center of Papardo Hospital, Messina

Organisation
Ekuberg Pharma

Funder(s)

Funder type

Funder Name
Ekuberg Pharma

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available