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Adhesion study of Flectoparin® Tissugel following plaster application to the lower leg (supra-malleolar area) in healthy volunteers

Submission date
25/08/2017

Recruitment status
No longer recruiting

Registration date
05/09/2017

Overall study status
Completed

Last Edited
29/08/2017

Condition category
Other

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

Plain English summary of protocol

Background and study aims
In a previous study conducted with healthy volunteers, the DHEP-Heparin medicated plaster was applied to the front thigh, reinforced using a loose fitting elastic net sleeve, and investigated under three non-standard treatment conditions (moderate exercise, under occlusion, and moderate heat exposure) in comparison to the reference condition of rest without occlusion. The results showed that all plasters under all four conditions adhered to at least 75% of the application area. All plasters adhered for ≥ 90% of the application area for most participants during moderate exercise and under occlusion. The aim of this study is to assess the adhesion of the DHEP-Heparin medicated plaster for the intended wear period of 24 hours.

Who can participate?
Healthy volunteers aged 18-55

What does the study involve ?
Participants are treated with two DHEP-Heparin medicated plasters on the lower part of the right and left leg. One plaster is applied without reinforcement and one plaster is applied with reinforcement with either elastic net or corner taping. Adhesion of the plasters is assessed after 4, 8, 12, 16, 20 and 24 hours.

What are the possible benefits and risk of partecipating ?
No specific benefits for the participants are foreseen. The application of two DHEP-Heparin plasters is considered to be safe.

Where is the study run from?
CROSS Research Phase I Unit (Switzerland)

When is the study starting and how long is it expected to run for?
December 2016 to February 2017

Who is funding the study?
IBSA Institut Biochimique SA (Switzerland)

Who is the main contact?
Dr Milko Radicioni

Contact information

Type(s)
Scientific

Contact name
Dr Milko Radicioni

ORCID ID
http://orcid.org/0000-0002-3940-8375

Contact details
CROSS Research S.A. – Phase I Unit
Via F.A. Giorgioli 14
Arzo
Switzerland
CH-6864

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Study CRO-PK-17-317 - Sponsor code 17CH/FHp01

Study information

Scientific Title
Adhesion study of Flectoparin® Tissugel following plaster application to the lower leg (supra-malleolar area) in healthy volunteers

Study objectives
Assess DHEP-Heparin medicated plaster (Flectoparin® Tissugel) adhesion to the skin at multiple adhesion time points up to 24 h following lower part of the leg application in healthy men and women.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Comitato Etico Cantonale, Canton Ticino, Switzerland,09/02/2017, ref: CE3172, BASEC (Business Administration System for Ethics Committee) Nr. 2017-00193

Study design
Single-centre single-dose one-period randomised adhesion assessment study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
DHEP-medicated plaster

Interventions
All enrolled subjects received the application of two investigational plasters, one without reinforcement (PW) on one leg (right or left) and one with reinforcement (PRN or PRT), applied concurrently to the lower part of the leg just above the malleolus. Half of the plasters for PR treatment were reinforced with an elastic net (PRN) and half with four 7 cm long tapes applied to the four corners of the medicated plaster (PRT). The randomisation list was computer-generated by the Department of Biometry at the Contract Research Organization (CRO) using the PLAN procedure of SAS Version 9.3, and supplied to the study site prior to study start. Investigational plasters were applied in the morning (08:00±1 h) and kept in place for 24 h.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Diclofenac-N-(2hydroxyethyl)-pyrrolidine (DHEP) medicated plaster formulated with heparin (Flectoparin® Tissugel, IBSA, Switzerland)

Primary outcome measure
Mean adhesion score for the investigational plaster without reinforcement (PW), derived from the individual adhesion scores representing the highest degree of detachment at each assessment time point averaged across all the equally spaced time points (4, 8, 12, 16, 20 and 24 h post-application)

Secondary outcome measures
1. Mean adhesion score for the investigational plaster with reinforcement (secured either by elastic net [PRN] or corner taping [PRT]), derived from the individual adhesion scores representing the highest degree of detachment at each assessment time point averaged across all the equally spaced time points (4, 8, 12, 16, 20 and 24 h post-application)
2. Assessment of plaster adhesion as a percentage of total plaster area for PW, PRN and PRT application at 4, 8, 12, 16, 20 and 24 h post-application
3. Proportion of subjects with an adhesion score representing the highest degree of detachment ≥ 2 at any time point for PW, PRN and PRT application (4, 8, 12, 16, 20 and 24 h post-application)
4. Time to an adhesion score ≥ 2 for PW, PRN and PRT application, assessed at 4, 8, 12, 16, 20 and 24 h post-application
5. Frequency of adhesion scores representing the highest degree of detachment at each time point and across all time points for PW, PRN and PRT application (4, 8, 12, 16, 20 and 24 h post-application)
6. Mean adhesion score for both the investigational plaster without reinforcement (PW) and with reinforcement (PRN, PRT), derived from the individual adhesion scores representing the highest degree of detachment at each DAILY assessment time point (4 to 12 h post application) averaged across all the DAILY assessment time points
7. Mean adhesion score for both the investigational plaster without reinforcement (PW) and with reinforcement (PRN, PRT), derived from the individual adhesion scores representing the highest degree of detachment at each NIGHT assessment time point (16 to 24 h post application) averaged across all the NIGHT assessment time points

Overall study start date
20/12/2016

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Informed consent: signed written informed consent before inclusion in the study
2. Males/females, 18-55 years old inclusive
3. Body Mass Index (BMI): 18.5-30 kg/m2 inclusive
4. Vital signs: systolic blood pressure (SBP) 100-139 mmHg, diastolic blood pressure (DBP) 50-89 mmHg, heart rate (HR) 50-90 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study
6. Contraception and fertility (females only): females of child-bearing potential had to use at least one of the following reliable methods of contraception:
6.1. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit
6.2. A non-hormonal intrauterine device or female condom with spermicide or contraceptive sponge with spermicide or diaphragm with spermicide or cervical cap with spermicide for at least 2 months before the screening visit
6.3. A male sexual partner who agreed to use a male condom with spermicide
6.4. A sterile sexual partner

Female participants of non-child-bearing potential or in post-menopausal status for at least 1 year were admitted. For all female subjects, pregnancy test result had to be negative at screening and at each scheduled evaluation.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Both

Target number of participants
Twenty-eight (28) subjects were enrolled in the study as planned

Key exclusion criteria
1. Electrocardiogram (12-leads, supine position): clinically significant abnormalities.
2. Physical findings: clinically significant abnormal physical findings which could interfere with the objectives of the study.
3. Laboratory analyses: clinically significant abnormal laboratory values indicative of physical illness
4. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the investigator considered could affect the outcome of the study
5. Diseases: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that could interfere with the aim of the study
6. Application site: diseased-skin, skin wounds or open injuries at the applications site
7. Medications: medications, including over the counter medications and herbal remedies, in particular nonsteroidal anti-inflammatory drugs (NSAIDS) and medications containing diclofenac, for 2 weeks before the start of the study. Hormonal contraceptives for females were allowed
8. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval was calculated as the time between the first calendar day of the month that followed the last visit of the previous study and the first day of the present study
9. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [>1 drink/day for females and >2 drinks/day for males, defined according to the USDA Dietary Guidelines 2015-2020], caffeine (>5 cups coffee/tea/day) or tobacco abuse (≥10 cigarettes/day)
10. Drug test: positive result at the drug test at screening
11. Alcohol test: positive alcohol breath test at day -1
12. Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study; vegetarians
13. Pregnancy (females only): positive or missing pregnancy test at screening or day -1, pregnant or lactating women

Date of first enrolment
21/02/2017

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
Switzerland

Study participating centre
CROSS Research Phase I Unit
Via F. A. Giorgioli 14
Arzo
6864

Sponsor information

Organisation
IBSA Institut Biochimique SA

Sponsor details
Via del Piano
Pambio-Noranco
Switzerland
CH 6915

Sponsor type
Government

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Government

Funder Name
IBSA Institut Biochimique SA

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
28/02/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository.

IPD sharing plan summary
Stored in repository