

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

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|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>25/08/2017   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>05/09/2017 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>29/08/2017       | <b>Condition category</b><br>Other                | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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  $\geq 90\%$  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 participating ?

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

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## Additional identifiers

**Protocol serial number**  
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

**Primary study design**  
Interventional

## **Study design**

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

## **Study type(s)**

Treatment

## **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(s)**

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)

## **Key secondary outcome(s)**

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  $\geq 2$  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  $\geq 2$  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

#### **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/m<sup>2</sup> 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

#### **Healthy volunteers allowed**

No

#### **Age group**

Adult

#### **Lower age limit**

18 Years

#### **Upper age limit**

55 Years

#### **Sex**

All

### **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 ( $\geq 10$  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**

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# Sponsor information

## Organisation

IBSA Institut Biochimique SA

## ROR

<https://ror.org/051tj3a26>

# Funder(s)

## Funder type

Government

## Funder Name

IBSA Institut Biochimique SA

# Results and Publications

## 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