A phase I, open label clinical trial in healthy volunteers, to assess and characterize the effect of FIRTECH infrared patch on tissue perfusion, oxygenation and local microcirculation.

Published: 19-08-2021
Last updated: 05-04-2024

Primary* To assess and characterize the local effect of the FIRTECH patch on local microcirculation.Secondary* To evaluate the effect of the FIRTECH patch on tissue oxygenation and perfusion.* To evaluate the local effect of the FIRTECH patch on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON50771

Source
ToetsingOnline

Brief title
FIRTECH local blood microcirculation

Condition

- Muscle disorders

Synonym
muscle strain

Research involving
Human

Sponsors and support

Primary sponsor: Sanofi Aventis Groupe
Source(s) of monetary or material Support: Sanofi Aventis Groupe

Intervention

Keyword: FIRTECH, Infrared, Microcirculation

Outcome measures

Primary outcome

Blood flow as measured with basal flow through laser speckle contrast imaging

(LSCI)

Secondary outcome

* Near-infrared spectrometry (NIRS). Change from baseline of the following

parameters will be analyzed:

o Blood flow measured as slope of hemoglobin increase in the arm during venous

occlusion

o Oxygen consumption measured as desaturation slope during arterial occlusion

o Reactive hyperemia measured as saturation slope after arterial occlusion

o Duration of reactive hyperemia measured as time to return to baseline after

arterial occlusion

* Laser speckle contrast imaging (LSCI) with post occlusive reactive hyperemia

(PORH) and local thermal hyperemia (LTH) challenges. Change from baseline of

the following parameters will be analyzed:

o Peak flow after arterial occlusion

o Peak flow during thermal hyperemia

o Plateau flow during thermal hyperemia

* Side-stream darkfield microscopy after tape stripping (SDFM). Change from baseline of the following parameters will be analyzed:

o Number of vessels, vessel density, perfused number of vessels, perfused vessel density

* Multispectral imaging (MSI). Change from baseline of the following parameters will be analyzed:

o Skin color, skin texture, skin redness level, skin melanin level

* Thermography. Change from baseline of the following parameters will be analyzed:

o Skin temperature

* AE/SAEs will be recorded from the time of informed consent until the end of the study. The following parameters will be analyzed:

o Pre- and post-treatment AEs

o TEAEs

* Description of any local sensation

Study description

Background summary

The FIRTECH patch contains titanium dioxide which re-emits infrared (IR) energy emitted by the human body. Titanium dioxide belongs to the category of molecules with a high emittance, the intrinsic ability to "receive" and "re-emit" at specific wavelengths. Specifically, the emittance of titanium dioxide is in a range of IR frequencies that have an interesting therapeutic aspect as they belong to the far-infrared spectrum (FIR). The IR radiation lies on the wavelength spectrum at 750 nm to 1000 *m, the frequency ranges from 400 terahertz (THz) to 0.3 THz, and the photon energy ranges from 1.24 meV to 1.7 eV. According to recent scientific hypotheses, reflection of FIR energy normally emitted from body heat back to the body causes an increase in the surface microcirculation of the skin through increase in nitric oxide release. FIR energy treatments have been studied in a wide range of clinical pathologies such as chronic pain, dysmenorrhea and wound healing.

In this study, the FIRTECH patch will be applied to the skin of healthy volunteers for 31 hours and skin microcirculation will be assessed non-invasively with several imaging techniques. Nitric oxide dependent vasodilation will be assessed with local thermal hyperemia (LTH) challenges during laser speckle contrast imaging (LSCI), general skin microcirculatory and flow function will be assessed with occlusion-reperfusion (PORH) LSCI challenges and skin temperature will be assessed with thermography. Additionally, muscle oxygen consumption and blood flow will be assessed with near-infrared spectroscopy (NIRS). Skin microcirculation will be filmed with side-stream dark field microscopy (SDFM) and multispectral images (MSI) will be taken to assess skin light absorption in different wavelength ranges. The test battery will give an overview of effects of the FIRTECH patch on microcirculation as well as give insight in the underlying physiological mechanisms of action.

Study objective

Primary
* To assess and characterize the local effect of the FIRTECH patch on local microcirculation.

Secondary
* To evaluate the effect of the FIRTECH patch on tissue oxygenation and perfusion.
* To evaluate the local effect of the FIRTECH patch on skin temperature.
* To assess the local safety and tolerability of FIRTECH patch.

Study design

This is an open label, randomized, controlled, interventional phase I clinical

trial.

Intervention

FIRTECH patch

Study burden and risks

The risk associated with the application of the patch are minimal. Earlier studies as described above have shown only mild and manageable local adverse events. The FIRTECH patch sticking strength is also not sufficient to cause skin damage. The pharmacodynamic assessments in the study in the form of imaging will allow fulfilment of the study-objectives mostly non-invasively, with minimal subject burden due to blood draws and tape stripping.

Contacts

Public
Sanofi Aventis Groupe

Rue la Boétie 54
Paris 75008
NL
Scientific
Sanofi Aventis Groupe

Rue la Boétie 54
Paris 75008
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Signed informed consent prior to any study-mandated procedure
2. Healthy male or female subjects, 18 to 55 years of age, inclusive.
3. Body mass index (BMI) between 18 and 30 kg/m2, inclusive at screening, and with a minimum weight of 50 kg.
4. Has the ability to communicate well with the Investigator in the Dutch language and willing to comply with the study restrictions.

Exclusion criteria

1. Evidence of any active or chronic disease or condition that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would pose an unacceptable risk to the subject in the opinion of the investigator (following a detailed medical history, physical examination, vital signs (systolic and diastolic blood pressure, pulse rate, body temperature) and12-lead electrocardiogram (ECG)). Minor deviations from the normal range may be accepted, if judged by the Investigator to have no clinical relevance.
2. Clinically significant abnormalities, as judged by the investigator, in laboratory test results (including hepatic and renal panels, complete blood count, chemistry panel and urinalysis). In the case of uncertain or questionable results, tests performed during screening may be repeated before patch side location randomization to confirm eligibility or judged to be clinically irrelevant for healthy subjects.
3. Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg at screening.
4. Use of any medications (prescription or over the counter [OTC]), within 14 days of study product administration, or less than 5 half-lives (whichever is longer). Exceptions are paracetamol (up to 4 g/day) and ibuprofen (up to 1g/day). Other exceptions will only be made if the rationale is clearly documented by the investigator.
5. Use of any vitamin, mineral, herbal, and dietary supplements within 7 days of study product administration, or less than 5 half-lives (whichever is longer). Exceptions will only be made if the rationale is clearly documented by the investigator.
6. Participation in an investigational drug or device study (last dosing of previous study was within 30 days prior to first dosing of this study).
7. History of abuse of addictive substances (alcohol, illegal substances) or current use of more than 21 units alcohol per week, drug abuse, or regular user of sedatives, hypnotics, tranquillizers, or any other addictive agent
8. Positive test for drugs of abuse at screening.
9. Alcohol will not be allowed from at least 24 hours before screening.

10. Active smoker (i.e. on average >3 cigarettes per day in the last 3 months)
11. Excess of caffeine consumption (more than eight cups of coffee or equivalent per day)
12. Any confirmed significant allergic reactions (urticaria or anaphylaxis) against any drug, or multiple drug allergies (non-active hay fever is acceptable).
13. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening or intention to donate blood or blood products during the study.
14. If a woman, pregnant, or breast-feeding, or planning to become pregnant during the study.
15. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or interpretation of the results such as drug or alcohol dependence or psychiatric disease.
16. Any tattoos, body modifications or other impediments to imaging present in areas to be assessed, i.e. right and left arm and back.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-09-2021
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	FIRTECH patch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-08-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL77899.100.21

Study results