

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Multicentre, open-label post-marketing follow-up observational study to evaluate the efficacy/tolerability of the Philips BlueTouch Pain Relief Patch in the daily routine treatment of back pain

Trial Acronym

BlueTouch PRP 2013/14

URL of the trial

[---]*

Brief Summary in Lay Language

Often unusual physical stresses lead to pain in the neck or the drawing in the back. Often back pain based rather on everyday conditional triggers, such as an incorrect posture at work or lack of exercise. If this error does not counteracted, can occur which significantly restrict us in everyday recurring, so-called chronic pain and stress.

The three mechanisms of action of blue light:

The blue LED light penetrates the skin and releases heat that can be felt immediately. The innovative effect, however, lies not in the heat effect. Crucial for pain relief are the body's processes around the molecule nitric oxide (NO), whose release is stimulated by the application with blue LED light.

In this non-interventional study, there will be collected data on the efficacy and tolerability of the Philips Blue Touch Pain Relief Patch in adult patients with stress- related low back/dorsal and / or shoulder/neck pain under the terms of the practical everyday health care.

Brief Summary in Scientific Language

This non-interventional prospective post-marketing observational field study will be conducted to document the efficacy and tolerability/safety of the Philips BlueTouch Pain Relief Patch in routine clinical practice 'on-label' use at the practices of pain specialists, general practitioners, as well as orthopedic, internal and neurologic specialists, and to compare them with that reported in randomized controlled clinical trials. Target population of this study are adult patients with non-specific localized pain in the upper and/or lower back in whom a treatment with the Philips BlueTouch Pain Relief Patch is indicated.

A special focus of this study lies on the identification of demographic and/or clinical characteristics of optimal responders to the Philips BlueTouch Pain Relief Patch.

In addition to analgesic efficacy, functional restoration and health-related quality of life, i.e. the patient's subjective overall well-being, are increasingly targeted aspects in pain medicine and evolve into a key parameter for successful pain management. Particular attention focus therefore on the evaluating of the influence of the Philips BlueTouch Pain Relief Patch on patients' functionality and ability to participate in daily life activities as well as associated health-related quality of life changes by the use of validated instruments recommended by the German Pain Society (Deutsche Gesellschaft für Schmerztherapie, DGS), the German chapter of the International Association for the Study of Pain (Deutsche Schmerzgesellschaft), and the German Pain League (Deutsche Schmerzliga, DSL).

This non-interventional trial intends also to record relevant data on the tolerability and safety of the Philips BlueTouch Pain Relief Patch during routine use in back pain patients. It is expected to obtain additional information regarding the influence of the Philips BlueTouch Pain Relief Patch on functionality and quality of life in a patient population suffering from different types of back pain which naturally may differ in demographic and baseline characteristics as well as prognosis and allowed co-medication in comparison to those patient populations usually enrolled in randomized controlled trials.

Organizational Data

- DRKS-ID: **DRKS00005707**
- Date of Registration in DRKS: **2014/03/25**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **F-2014-019 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- Free text: **Localized unspecific pain of the upper or lower back**

Interventions/Observational Groups

- Arm 1: **Single arm, multicentre, open-label post-marketing follow-up observational study to evaluate the efficacy/tolerability of the Philips BlueTouch Pain Relief Patch in the daily routine treatment of back pain with the Philips Bluetouch Pain Relief Patch**



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Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome on efficacy and tolerability:
Queries based on two "verbal rating scales" in the physician's interim documentation (after 1 week of therapy) as well as in the physician's end documentation (after 2 weeks of therapy) compared to the previous non-drug or drug treatments.

Secondary Outcome

- **Patient-relevant aspects regarding pain-related impairment of activities of daily life**
- **Overall quality of life**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Doctor's Practice **Aachen**
- Doctor's Practice **Augsburg**

- Doctor's Practice **Bad Bergzabern**
- Doctor's Practice **Bad Lippspringe**
- Doctor's Practice **Bad Oeynhausen**
- Doctor's Practice **Bad Pyrmont**
- Doctor's Practice **Bad Segeberg**
- Doctor's Practice **Bad Vilbel**
- Doctor's Practice **Berlin**
- Doctor's Practice **Berlin**
- Doctor's Practice **Berlin**
- Doctor's Practice **Berlin**
- Doctor's Practice **Bielefeld**
- Doctor's Practice **Böblingen**
- Doctor's Practice **Böhlen**
- Doctor's Practice **Bonn**
- Doctor's Practice **Dortmund**
- Doctor's Practice **Duderstadt**
- Doctor's Practice **Düsseldorf**
- Doctor's Practice **Eisenach**
- Doctor's Practice **Emden**
- Doctor's Practice **Essen**
- Doctor's Practice **Fellbach**
- Doctor's Practice **Frankfurt a.M.**
- University Medical Center **Klinikum der Johann Wolfgang Goethe-Universität,
Frankfurt a.M.**
- Doctor's Practice **Frankfurt a.M.**
- Doctor's Practice **Gingen**
- Doctor's Practice **Göppingen**
- Doctor's Practice **Göppingen**
- Doctor's Practice **Göttingen**
- Doctor's Practice **Groß Grönau**
- Doctor's Practice **Haan**
- Doctor's Practice **Hamburg**
- Doctor's Practice **Hammelburg**

- Doctor's Practice **Hannover**
- Doctor's Practice **Herbsleben**
- Doctor's Practice **Hohenwart**
- Doctor's Practice **Homburg**
- Doctor's Practice **Homburg**
- Doctor's Practice **Hünfeld**
- Doctor's Practice **Jena**
- Doctor's Practice **Kassel**
- Doctor's Practice **Kassel**
- Doctor's Practice **Kevelaer**
- Doctor's Practice **Köthen**
- Doctor's Practice **Krefeld**
- Doctor's Practice **Lahnau**
- Doctor's Practice **Laufen**
- Doctor's Practice **Leipzig**
- Doctor's Practice **Limburgerhof**
- Medical Center **Klinik Löwenstein, Löwenstein**
- Doctor's Practice **Ludwigshafen am Rhein**
- Doctor's Practice **Ludwigshafen am Rhein**
- Doctor's Practice **Lünen**
- Doctor's Practice **Magdeburg**
- Doctor's Practice **Mainz**
- Doctor's Practice **Marburg-Wehrda**
- Doctor's Practice **Miltenberg**
- Medical Center **St. Josef Krankenhaus, Moers**
- Doctor's Practice **Mönchengladbach**
- Doctor's Practice **München**
- Doctor's Practice **München**
- Doctor's Practice **München**
- Medical Center **Kliniken Nagold, Nagold**
- Doctor's Practice **Neuhardenberg**
- Doctor's Practice **Nürnberg**

- Doctor's Practice **Passau-Kohlbruck**
- Doctor's Practice **Potsdam**
- Doctor's Practice **Rehna**
- Doctor's Practice **Riedlhütte**
- Doctor's Practice **Rosenheim**
- Medical Center **St. Antonius Krankenhaus, Schleiden**
- Doctor's Practice **Schwalbach**
- Doctor's Practice **Schwerte**
- Doctor's Practice **Soest**
- Doctor's Practice **Solingen**
- Doctor's Practice **Spiesen-Elversberg**
- Doctor's Practice **Stadtroda**
- Doctor's Practice **Wangen**
- Doctor's Practice **Wegberg**
- Doctor's Practice **Weilheim**
- Doctor's Practice **Welzheim**
- Doctor's Practice **Wipperfürth**
- Doctor's Practice **Witzenhausen**
- Medical Center **Krankenhaus Sankt Josef, Wuppertal**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/18**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patient age ≥ 18 years
Patient is able and willing to understand a written informed consent
Patient suffers from back pain

Patient is able to comply with the study characteristics and to fulfill its requirements, according to the investigator's evaluation

Exclusion criteria

Patient is currently or was within the previous 4 weeks enrolled in an interventional clinical trial

Patient is actually suffering from conditions and illnesses that might interfere with the trial purpose, according to the investigator's evaluation

Patient has a history of substance abuse (drug or alcohol) or any other factor (e.g., serious psychiatric condition) that could limit the subject's ability to comply with trial procedures

Patient has insufficient knowledge of the German language to understand the Informed Consent Form and/or trial questionnaires

Patient is/was involved in the planning and conduct of the trial (applies to either Philips staff, staff participating at the trial site or staff of the logistics CRO)

Patient suffers from any condition or illness as listed in the contraindications section of the BlueTouch Pain Relief Patch user manual

Patient has used the Philips BlueTouch Pain Relief Patch before

Addresses

■ Primary Sponsor

**Philips Consumer Lifestyle
Amstelplein 2
1096 Amsterdam
Netherlands**

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ Contact for Scientific Queries

**Schmerz- und Palliativzentrum Göppingen Deutsche Gesellschaft für
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■ **Contact for Public Queries**

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■ **Collaborator, Other Address**

O.Meany Medical Data & Project Management GmbH

Theodorstraße 1

90489 Nürnberg

Germany

Telephone: **0911-5068210**

Fax: [---]*

E-mail: [---]*

URL: [---]*

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Philips Consumer Lifestyle, Innovation Site Eindhoven

Ms. Dr. Elke Naujokat

High Tech Campus 37, p.041

5656 Eindhoven

Netherlands

Telephone: **0031631974213**

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Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.