UNEEG™ medical

Clinical Investigation Plan

U009

Safety and performance of short- and long-term Baseplates for attaching the Marco Recorder

(Brand name: UNEEG Episight)

September 2021 - December 2022

SYNOPSIS OF THE CLINICAL INVESTIGATION

Title	**Duration**
Safety and performance of short- and long-term Baseplates for attaching the Marco Recorder	The study is divided into two parts. In the initial part (Main part/Part I) of the study, the inclusion period is up to 42 days for each subject, where the test period is divided into 2 periods of 17-18 days each. After the initial part of the study, an interim analysis will be performed and the result will be used to conduct a subsequent study period (Extension part/Part II) of up to 42 days including additional subjects.

Introduction

UNEEG™ medical is developing a new version of the 24/7 EEG™ SubQ system, which is used for ultra long-term ambulatory EEG recording. The current system consists of an implantable electrode and an external Recorder connected to a "disc" with a cable. The Recorder acts as a power source and data storage unit. When the disc is placed on the skin over the implant it receives a magnetic inductive link that 1) powers the electrode, and 2) transfers the recorded EEG signals to the Recorder. UNEEG™ medical is developing a new external power and storage unit with the in-house development name "Marco Recorder", which is a smaller and cable-free replacement of the current version. The new Recorder is attached to the skin behind the ear by mounting it in a Baseplate consisting of a double adhesive and a plastic frame.

The purpose of this clinical investigation is to test the safety and performance of short- and long-term Baseplates constructed with different types of biocompatible adhesives. The short-term Baseplate must be replaced daily and the long-term every four days. The outcome of the investigation will be used by UNEEG™ medical to evaluate two Baseplates, one short-term and one long-term Baseplate, suitable for attaching the Marco Recorder to the skin behind the ear.

Objective

The primary objective of the study is to demonstrate the skin-friendliness of two types of Baseplates (i.e., adhesives) after up to 35 days repeated use on the skin behind the ear.

The secondary objectives are to

- Demonstrate effectiveness of the Baseplate to hold the Recorder in place on the skin behind the ear.
- Evaluate safety of the Baseplate (i.e., adhesives).
- Evaluate subject-reported performance of the different types of Baseplates and the Recorder.
- Evaluate subject-reported satisfaction.

It is hypothesised that the various Baseplates can 1) hold a Recorder in place for 1 or up to 4 days depending on the type of adhesive, 2) be worn and removed gently without significantly irritating or damaging the skin.

Endpoints

Primary endpoint

The trans epidermal water loss (TEWL) is captured to evaluate skin barrier functionality, i.e. to measure potential skin damage caused by repeated use of the Baseplate and Recorder.

Secondary endpoints

Skin assessment endpoints

- Hydration: An objective skin assessment based on conductance to measure the skin's ability to retain water.
- Erythema: An objective skin assessment based on reflectance spectrophotometry to measure reddening.
- Pain upon removal is assessed by a Visual Analog Score (VAS) on a scale between 1-10).
- Skin condition is based on visual inspection by investigator (including a photo) and by subject -report.

Safety endpoint

- Nature and frequency of adverse events during the study and their severity, outcomes, and relationship to the Baseplate and Recorder.

Performance & effectiveness endpoints (subject-reported)

- Daily: Subject questionnaire on physical activity and complications with devices.
- End of each test period: Subject questionnaire on user experience.

User Satisfaction Endpoint

- End of study: Subject satisfaction questionnaire.

Design and Methods

The first study part (Main part/Part I) is a randomised, controlled setup with an initial 2x2 cross-over design consisting of two test periods of 17-18 days each. Thirty subjects will be included in this part, and each individual subject will test two short-term Baseplates (type A behind one ear and type B behind the other ear) in one test period (17-18 days) and two long-term Baseplates (type C and D) in a second test period of the same duration. The order of the two test periods (short/long-term Baseplate) and the site of attachment (left/right ear) will be randomised. Following this study part (Part I), an interim analysis will be performed to select the most promising short-term and long-term Baseplate (i.e., adhesive) to be tested in the Extension part/Part II with a modified design. Thus, in the second study part (Extension part/Part II) 10 additional subjects will be included to test the selected Baseplates in a randomized controlled setup for a period of 35 days.
The study will take place in Denmark at Bispebjerg Hospital.

Population/subjects

The investigational population consists of 40 healthy subjects who comply with the following selection criteria:

Inclusion Criteria:

- Informed consent obtained, and letter of authority signed before any study related activities
- Are at least 18 years of age and have full legal capacity
- Have healthy skin behind the ear

Exclusion Criteria:

- Pregnant or breastfeeding[1]
- Known allergic responses to the adhesives
- Treatment with corticosteroids, either as a cream in the area behind the ear or systemically (tablet or injection) within the last month
- Subject is unable or does not have the necessary assistance to properly operate the device system

[1] Pregnancy is screened for through a pregnancy test before inclusion of fertile women.

Investigational device and comparator
The investigational devices are non-CE marked biocompatible Baseplates and a non-functional Recorder. Four different Baseplates are identified as Baseplate A, B, C and D. Type A and B are tested for short-term (daily) use, and type C and D are tested for long-term (4 days) use. All types of Baseplates are biocompatible and intended for attaching other medical devices (1–4).
Investigation approval
The investigation will be approved by the local ethics committee (EC) and the regulatory authorities (LMS) in Denmark before initiating the investigation.