The Evaluation of the Toffee Mask for the Treatment of Obstructive Sleep Apnea

NCT03142438

DATE: 12th April 2017

Fisher & Paykel HEALTHCARE

Fisher & Paykel
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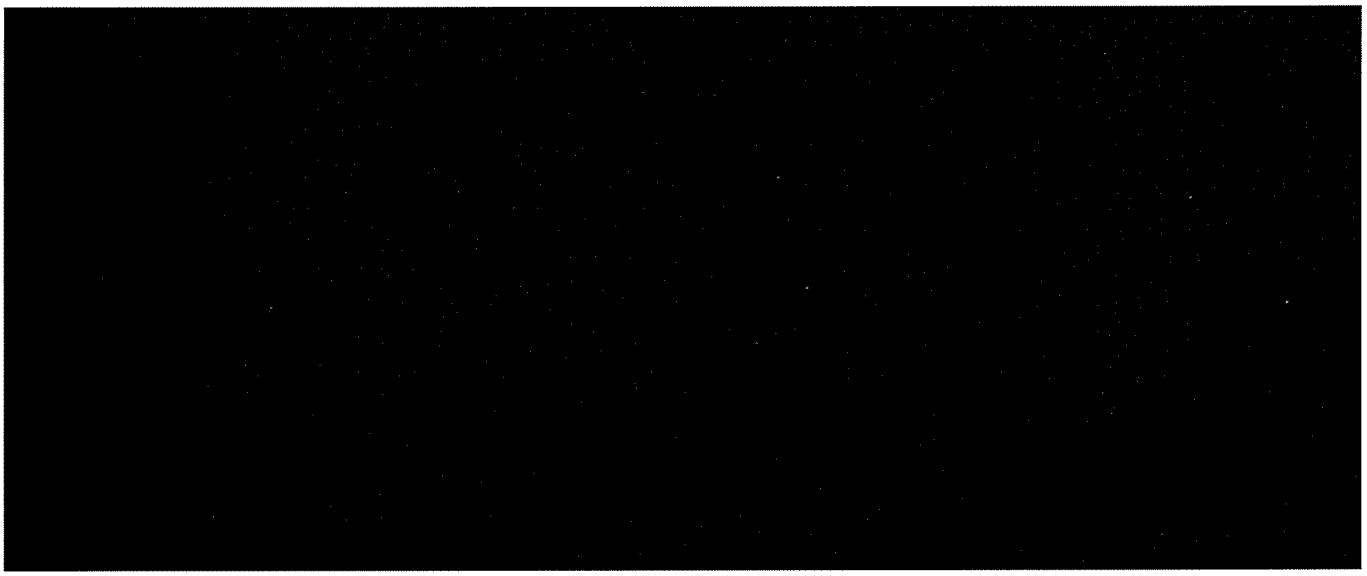
Clinical Investigation Plan

12 April 2017



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[redacted]

1. Revision History

Revision	[redacted]	Date	[redacted]
A	[redacted]	12 Apr 2017	[redacted]

1.1. List of Abbreviations

[redacted]

[redacted]

[redacted]

2. Document Information

2.1. Purpose and Scope

The purpose of the trial is to evaluate the performance, comfort and ease of use of the [redacted] mask in the home environment.

2.2. Confidentiality Statement

This document contains confidential information belonging to Fisher & Paykel Healthcare and is provided for the sole purpose of enabling an evaluation of a possible collaboration with Fisher & Paykel Healthcare to undertake the proposed clinical research. This document must be maintained in a confidential manner at all times and any disclosure, distribution or reproduction of this document outside the intended purpose is prohibited.

2.3. Persons Authorized to Amend the CIP

[redacted]

2.4. Monitoring Arrangements

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

2.5. Data Management

[redacted]

3. Investigator Information

3.1. Primary Investigator

Name: Dr. David Ostransky, MD

Address: 2801 S.Hulen St, Suite 600, Fort Worth, TX 76109

Email: dostransky@NTLSC.com

Phone: 817.731.0230

Professional Position: Board Certified Sleep Specialist

3.2. Coordinating Investigator

Name: Bobbie Lambert, RPGST

Address: 2801 S.Hulen St, Suite 600, Fort Worth, TX 76109

Email: blambert@NTLSC.com

Phone: 817.731.0230

Professional Position: Clinical Sleep Educator, Sleep Director & Clinical Liaison

[redacted]

[redacted]

3.3. Institution

Name: North Texas Lung & Sleep Clinic

Address: 2801 S.Hulen St, Suite 600, Fort Worth, TX 76109

Email: dostransky@NTLSC.com

Phone: 817.731.0230

Country of residence: United States of America

4. Sponsor Information

4.1. Primary Sponsor Details

Name of Business: Fisher & Paykel Healthcare Limited

Address: 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand.

Name of Sponsor contact person: Hanie Yee

Phone: +64 9 5740123 Ext 7909

Email: Hanie.Yee@fphcare.co.nz

Profession: Clinical Research Manager

Country of residence: New Zealand

4.2. Overseas Representative

[redacted]

5. Device Information

5.1. Identification of the Medical Device

[redacted]

[redacted]

[redacted]

5.2. Device Risk Analysis and Management

[redacted]

6. Justification for a Clinical Trial

6.1. Synopsis

The investigation is a prospective, non-randomized, non-blinded, study. The investigation is designed to evaluate the performance, comfort and ease of use [redacted]

This study will be conducted in accordance with ICH/GCP guidelines. No deviation from the protocol will be implanted without prior review and approval of the sponsor except where it may be necessary to eliminate an immediate hazard to a research participant. In such case, the deviation will be reported to the sponsor as soon as possible. In this trial the sponsor and the investigator are the same company however the Sponsor will not be the investigator. To ensure roles are clearly defined and kept independent there will be a delegation of authority log to clearly define each individuals tasks.

6.2. Literature Review

[redacted]

[redacted]

6.3. Preclinical Testing

[redacted]

6.4. Previous Clinical Experience

[redacted]

6.5. Justification for Administration

[redacted]

7. Objectives of the Clinical Investigation

7.1. Hypothesis

[redacted]

7.2. Objectives

Primary objective:

- To evaluate the performance, comfort and ease of use of the [redacted] mask [redacted] in a home environment in regards to the participants' view of overall comfort, experience and satisfaction.

[redacted]

[redacted]

[redacted]

7.3. Population

Approximately 60-70 participants will be recruited for the trial by NTLSC.

[redacted]

After identification, the co-ordinating investigator or contact persons from the institutions (or those identified by delegation log) will contact potential participants and obtain informed consent from the subjects to be enrolled.

[redacted]

7.5. Essential Requirements of the Relevant Directive

[redacted]

8. Clinical Investigation Design

8.1. Type of Investigation

This is an open-label (investigators and participants are un-blinded and informed of intended treatment device) single arm study. [redacted]

8.2. Controls

No control group will be used in this study [redacted]

8.3. Bias

The F&P mask is non-blinded and distinguishable. Since the trial mask is the same for the entire population, this study is not blinded.

[redacted]

[redacted]

8.4. End Points

8.4.1. Primary Outcomes

- The F&P mask is comfortable to use for the participant as measured by the custom questionnaires and recorded during the interviews.
- The mask is easy to use, accepted by the participant and provides adequate treatment for OSA during in-home use, measured via participant feedback and PAP data download (if applicable)
- The acceptability of the mask [redacted] through interview feedback/ participant questionnaire .

8.4.2. Secondary Outcomes

- Seal performance as measured by leak measurements/PAP data (if applicable).

[redacted]

8.5. Variables

[redacted]

[redacted]

[redacted]

[redacted]

8.6. Measurements

[redacted]

8.7. Equipment

[redacted]

8.8. Inclusion / Exclusion criteria

Inclusion Criteria:

- Adult (22+ years of age)
- Able to give informed consent
- AHI ≥5 on diagnostic night
- Either prescribed APAP, CPAP or Bi-level PAP for OSA
- Fluent in spoken and written English

Exclusion Criteria:

- Inability to give informed consent
- Participant intolerant to PAP
- Anatomical or physiological conditions making PAP therapy inappropriate
- Current diagnosis of respiratory disease or CO_2 retention
- Pregnant or may think they are pregnant.

[redacted]

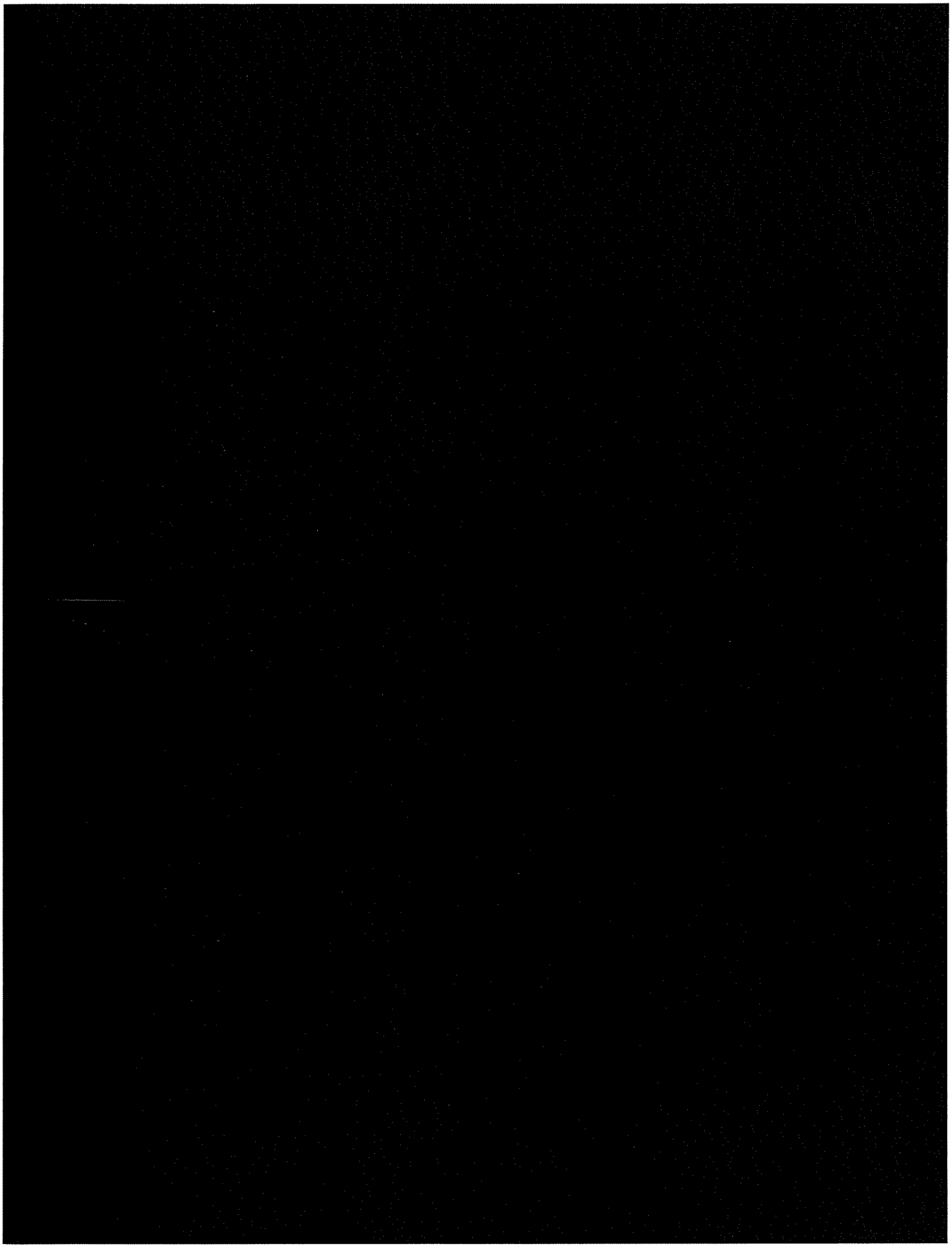
8.9. Point of Enrolment

Participants will be recruited; who are prescribed either APAP, CPAP or Bi-level PAP for OSA at NTLSC. The principal investigator (or those identified in the delegation log) will ask the subjects whether they are interested to take part in the trial. The participants who meet the inclusion/exclusion criteria and provide informed consent and will then be enrolled in to the trial. [redacted]

8.10. Participant Procedure

[redacted]

[redacted]



[redacted]

[redacted]

[redacted]

8.11. Withdrawal Criteria

Participants will be informed that they have the right to withdraw from the study at any time, without prejudice to their medical care, and are not obliged to state their reasons. The participants is informed that they can revert back to their usual therapy during the clinical investigation if they have reason to do so. Additionally the investigator may withdraw a participant at any time for the following reasons:

- Protocol Violation
- Safety concerns
- Serious illness
- Adverse event

The reason for participant discontinuation in the study is to be recorded in the CRF and source document.

8.12. Number of Trial Subjects

[redacted]

[redacted]

[redacted]

[redacted]

STATISTICAL CONSIDERATIONS

9.5. Description of the Statistical Design

Since the trial is to inform product development, no statistical design is required.

9.6. Sample Size

A minimum of 30 participants will be utilised for each investigation. According to the FDA guidance on Human Factors Engineering, a sample size of 30 will allow a mean of 99% of usability problems to be identified (minimum of 97%). This is deemed to be appropriate for this investigation as the product is in feasibility, and the intent is to assess the usability of the user interface to determine further design iterations.

9.7. Pass/Fail Criteria

There is no pass/fail criteria for this trial as the primary objective of the trial is to gain feedback [redacted]

[redacted]

9.8. Statistical Termination

No interim analysis will be conducted as statistical outcomes will not change the conduct of the study.

9.9. Statistical Procedure Deviations

Statistical procedure deviations will be reported to the principal investigator and the sponsor. Deviations from the original statistical plan will be explained in the final study report.

9.10. Selection Criteria

All participants who consent, and are fitted with a mask that they attempt to sleep on will be included in the analysis. Please see section 8.10 for information on participant flow throughout the trial.

9.11. Statistical Data Management

Fisher and Paykel Healthcare may consult an external statistician to assist with the analysis of the data.

10. Adverse Events and Termination

An Adverse Event (AE) is any adverse change from the participant's baseline condition, i.e., any unfavorable and unintended sign or symptom or disease that occurs during the course of the study, whether or not considered related to the PAP treatment. All clinically significant AEs occurring during the study that were not present prior to the commencement of PAP treatment, will be recorded in the CRF and source document and followed by the Investigator until resolution or stabilization occurs in accordance with GCP.

Serious AE's are considered to be AE's that result in any of the following outcomes, regardless of their relationship to the PAP treatment:

- Death
- A life-threatening AE
- In-patient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital abnormality/birth defect

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

10.3. Reporting Adverse Events

Any serious AE, due to any cause, that occurs during the study period, must be reported immediately (within the next business day) by telephone to the sponsor. In addition to the initial telephone report, a Serious Adverse Event form must be completed and sent via facsimile to the sponsor. All serious AE's must also be recorded on the AE page of the CRF. Additionally, all serious AE's must be reported to the Independent Review Board (IRB) as per the IRB's requirements.

[redacted]

10.4. Early Termination

The study may be discontinued at any time on the advice of the responsible investigator on the basis of new information regarding safety or efficacy. Additionally, the study may be terminated if progress is unsatisfactory. The following documentation is required if the appropriate party terminates a clinical trial.

10.5. Investigator

If the investigator terminates or suspends a trial without prior agreement of the sponsor, the investigator should inform the institution, where required by the applicable regulatory requirements and the investigator/institution should promptly inform the sponsor and the IRB, and should provide the sponsor and the IRB a detailed written explanation of the termination or suspension.

10.6. Sponsor

If the sponsor terminates or suspends a trial, the investigator should promptly inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly inform the IRB and provide the IRB a detailed written explanation of the termination or suspension.

10.7. Institutional Review Board (IRB) or Independent Ethics Committee (IEC)

If the IRB terminates or suspends its approval/favorable opinion of a trial the investigator should inform the institution, where required by the applicable regulatory requirements, and the investigator/institution should promptly notify the sponsor and provide the sponsor with a detailed written explanation of the termination or suspension.

[redacted]

[redacted]

[redacted]

[redacted]

13. References

1. Al Lawati N et al. Epidemiology, Risk Factors, and Consequences of Obstructive Sleep Apnea and Short Sleep Duration. Prog Cardiovasc Dis 2009; 51(4): 285-93.
2. Dungan G et al. Randomized Crossover Trial of the Effect of a Novel Method of Pressure Control (SensAwake) in Automatic Continuous Positive Airway Pressure Therapy to Treat Sleep Disordered Breathing. Journal of Clinical Sleep Medicine 2011; 7(3): 261-267.
3. Weaver T, Grunstein T (2008) Adherence to continuous positive airway pressure: the challenge to effective treatment. Proc Am Thorac Soc 15(5):173–178
4. Wolkove N, Baltzan M, Kamel H, Dabrusin R, Palayew M (2008) Long-term compliance with continuous positive airway pressure in patients with obstructive sleep apnea. Can Respir J 15(7):365–369
5. Prosise, G.L et al. Oral-nasal continuous positive airway pressure as a treatment for obstructive sleep apnea. Chest 1994; 106(1):180-186.
6. Massie CA and Hart RW. Clinical Outcomes related to Interface type in patients with Obstructive Sleep Apnea/Hypopnea Syndrome who are using Continuous Positive Airway Pressure. Chest 2003; 123:1112-1118.
7. Guidance for Industry and FDA Staff document. Applying Human Factors and Usability Engineering to Medical Devices. February 3,2016.

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