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STUDY: 'CONTINUOUS OPTICAL BLOOD PRESSURE MONITORING TO ASSESS THE THERAPEUTIC EFFECT OF CPAP TREATMENT IN PATIENTS WITH OBSTRUCTIVE SLEEP APNOEA. AVLA1 PROJECT'.

PRINCIPAL INVESTIGATOR and COORDINATOR: Dr. MIKEL AZPIAZU, OSI Araba Sleep Unit MD, H.Universitario Araba. Vitoria.

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We are writing to you to propose your participation in this research study, a collaborative project between the OSI Araba Sleep Unit and Cardiology Department. The study has been approved by the Basque Research Ethics Committee, in accordance with current legislation, and is being carried out in accordance with the principles set out in the Helsinki declaration and the standards of good clinical practice. Our intention is that you receive correct and sufficient information so that you can evaluate and judge whether or not you wish to participate in this study. Please read this information sheet carefully and we will answer any questions you may have. In addition, you can consult with the people you consider appropriate. If you have any doubts, you can contact the project coordinator (Mikel Azpiazu MD). If you do not wish to participate in this study, your CPAP treatment for sleep apnea will not be affected and the usual care process will be carried out in our unit.

The main objective of the project is to evaluate the therapeutic effect of CPAP therapy on blood pressure control in patients with sleep apnea with undiagnosed hypertension, by means of continuous blood pressure monitoring with a portable bracelet-type device (AKTIIA ®). Secondary objectives were to evaluate the effect of CPAP on cardiac function on these patients using echocardiography and, finally, to determine the usability and patient experience with this device.

AKTIIA is a non-invasive, automatic and continual (24/7) blood pressure and heart rate monitoring system using a comfortable wristband that measures optical photoplethysmography signals. Measurements from the wristband are synchronized with a mobile app via Bluetooth and this in turn with a cloud platform that stores the data. The system does not collect personally identifiable information from the patient (the patient is identified with an anonymous account credential provided by the company) and the data is stored on highly secure servers in Europe. No inconvenience or risk is expected from wearing the AKTIIA wristband during monitoring. For more information: https://aktiia.com/uk/

If you are considered a candidate for the study and agree to participate, you will initially undergo AKTIIA monitoring for one week to confirm that you have high blood pressure. If this is confirmed, an echocardiography, a non-invasive test performed by a cardiologist to assess the functioning of the heart, is performed. Subsequently, we schedule a face-to-face consultation to initiate CPAP treatment, to receive information about the treatment and care process. For participants with confirmed hypertension, once the appropriate CPAP therapeutic pressure for each participant is documented, AKTIIA monitoring is performed for 12 weeks. At the end of the monitoring, a face-to-face consultation is scheduled to assess the CPAP treatment, the monitoring data and to schedule a second control echocardiography. The patient is also given an anonymous usability survey to determine their experience and satisfaction with the AKTIIA device, thus ending their participation in this project. The wristband must be returned at the end of the study. Participants receive a final report on the results of the AKTIIA monitoring and the echocardiographic cardiological study, with indications for new studies and/or treatments if deemed necessary.

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report on the results of the AKTIIA monitoring and the echocardiographic cardiological study, with indications for new studies and/or treatments if deemed necessary.

Your participation in the study is completely voluntary. Refusing to participate does not imply any deterioration in the quality of care and treatment of your disease. Furthermore, you may withdraw from the study at any time, without having to give any explanation and without any impact on the care you receive (or may receive in the future). The study leader may decide, for medical or other reasons, to withdraw you from the study at any time if he or she thinks it is appropriate to do so.

The study data, together with other personal and clinical data, are recorded in a database. We inform you that you have the right to access, rectify and delete your data at any time without prejudice to your medical care or any loss of the benefits to which you are entitled. You can exercise this right by sending an email to: investigacionsueno@bioaraba.org

The register complies with the provisions of REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. You are informed that your personal data will be processed by Osakidetza - Basque Health Service. You are also requested to give your consent for this registration to be carried out in accordance with the requirements of European Regulation 2016/679 on Data Protection and Organic Law 3/2018, of 5 December, on the Protection of Personal Data and the guarantee of digital rights, which repeals Organic Law 15/1999, of 5 December, on the protection of personal data. No data will be transferred to third parties, unless legally obliged to do so. You can also find further information on data protection at the following website: https://www.osakidetza.euskadi.eus/protecciondatos

Based on the previous explanations, we request your consent for your participation in this study and the processing of your personal data for the purposes indicated above. The anonymity of the patients will be always maintained and to this end, no identifying data (e.g. your name) will appear in any of the analysis and/or study documents, but you will be assigned an identification code that will be used in all of them. In all written reports and publications, you will also not be identified. Only the project coordinator and the person responsible for the registry (Dr. Mikel Azpiazu) will keep the list that relates the names of the patients with the assigned reference codes in secure conditions. Only the principal investigator, the collaborating investigators who participate in the collection and management of these data and, exceptionally, the representatives of the regulatory bodies and the ethics committee will have access to the registry data in order to comply with legal and regulatory provisions. The results of data analyses and/or research studies shall always be presented in an aggregate form and never on an individual basis.

Your participation in this study will not involve any financial cost to you, nor will you be financially rewarded for it. The investigators will not receive any financial compensation for your participation in this study and have declared that they have no conflict of interest for this study. If you have any questions or would like more information, please do not hesitate to consult with the principal investigator who is asking you for this consent.

Whatever your decision, the entire research team would like to thank you for your time and attention. You are contributing to the better understanding and care of your disease which may benefit many people in the future.

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INFORMED CONSENT

STUDY: CONTINUOUS LONGITUDINAL MONITORING OF BLOOD PRESSURE USING A PORTABLE DEVICE IN PATIENTS WITH SLEEP APNOEA TREATED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE. AKTIIA OSA PROJECT.

I, (name and surname) .....

declare that I have been informed of the present study and:

- I have read and understood the information sheet I have been given.
- I was able to ask questions about the study.
- I have received sufficient information about the study.
- I understand that my participation is voluntary.
- I understand that I can withdraw:
  - Whenever I want
  - Without having to explain myself
  - Without any impact on my medical care
- I understand that my participation will not be detrimental to my health.
- I have been informed that my personal data will be protected and that the results of my personal assessment will be kept strictly confidential.
- I freely agree to participate in the study and consent to the access and use of my data under the conditions detailed in the patient information sheet.

I THEREFORE CONSENT

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Signature of patient

MIKEL AZPIAZU

Pneumologist

Sleep Unit OSI Araba

Project coordinator

Date ...../...../2024