Title of the study: Safety and Effectiveness Evaluation of the Sinusway™ Device for Endoscopy of the Nasal Cavity and Paranasal Sinuses in Conjunction with Sinus Balloon Dilation
NCT No.: NCT03390257
Date of document: 3 July, 2017

APPROVED
AS MODIFIED
Jul 31, 2017
WIRB®

INFORMATION FOR THE PATIENT

TITLE: Safety and Effectiveness Evaluation of the Sinusway™ Device for Endoscopy of the Nasal Cavity and Paranasal Sinuses in Conjunction with Sinus Balloon Dilation

PROTOCOL NO.: SD-001
WIRB® Protocol #20170263

SPONSOR: 3NT Medical

INVESTIGATOR: Jacob Johnson, MD
Suite 933
450 Sutter Street
San Francisco, California 94108
United States

STUDY-RELATED PHONE NUMBER(S): Jacob Johnson, MD
801-475-3000 (24 Hours)

You have been asked to participate in a clinical research study to evaluate the safety and performance of an investigational medical device called Sinusway ("the device"") for endoscopy of the nasal cavity and paranasal sinuses during Sinus Balloon Dilation.

The study is expected to include fifteen (15) participating men and women.

Purpose:
The purpose of the study is to evaluate the safety and performance of the Sinusway endoscope, in patients scheduled for Endoscopic Sinus Surgery with balloon sinus dilation by the ENT specialist.

Description of the Device:
Sinusway, developed by 3NT Medical, is a single-use disposable handheld endoscope 2.5mm in diameter, which is thinner and more flexible than other endoscopes. The endoscope includes a camera at its end and a working channel. The thin endoscope provides a means to visualize the nasal cavity and paranasal sinus space and to deliver irrigation to treat the sinus ostia (drainage openings) and spaces within the paranasal sinus cavities.

The findings made by the Sinusway endoscope will not be used for diagnostic purposes.

Procedure Summary:
Screening visit
Screening will take place within 2-30 days before the procedure. In this visit you will be asked about your medical condition and any medications you are taking. Vital signs such as blood

pressure and blood tests will be taken in this screening visit. CT examinations will be done to allow the physician to examine your sinuses in detailed cross-sections. If you already have recent CT, your doctor may use it rather than repeat it. You will be asked to complete questionnaire regarding your sinus disease. After this screening, you will be scheduled to undergo the procedure, which will also include evaluation with Sinusway endoscope.

Operation Visit
The Endoscopic sinus operation with sinus balloon dilation that you will undergo is the standard procedure that would normally be used to treat your condition; during this operation, the nasal cavity will also be evaluated by using the Sinusway endoscope.

Duration of the procedure:
During the procedure Sinusway endoscope will be used for about 20 minutes. No follow up is required.

Risks and Expected discomfort from Sinusway Nasal Endoscopy:
The Sinusway endoscope is basically a standard endoscope, which has better maneuvering capabilities because it is thinner and more flexible than other endoscopes. As such we assume that its associated risks are similar to those related to other endoscopes. As the device is investigational, the actual rate of adverse events is not known yet. There may be side effects which are not known at this time.

Minor and rare complications related to the use of nasal endoscopy include discomfort, nasal edema and nasal bleeding. Use of the Sinusway endoscope will increase the time it takes to complete your surgery.

All components of Sinusway endoscope are designed, manufactured and tested according to relevant international standards for medical devices, and the scope is provided sterile. The materials used in the Sinusway endoscope are routinely used and their biocompatibility is well known.

In addition, several simulation studies were performed to demonstrate that the system doesn't fail under conditions that may be applied during procedure. The combined results of all analyses and tests indicate that the Sinusway endoscope maintain its integrity during normal use.

Finally, the Sinusway endoscope combines, in its mode of operation, known principles of endoscopy and surgical techniques, which are well known and routinely used in a variety of procedures. Therefore, the Sinusway endoscope is not expected to pose new or higher risks than standard endoscopes used in the procedure you need to undergo.

Risks associated with Endoscopic sinus surgery with balloon dilation procedure:
Your physician will discuss potential complications of balloon sinus dilation with you. Balloon Sinus dilation is a generally safe and effective procedure for many patients seeking relief from uncomfortable and painful sinusitis symptoms. As with any medical intervention, potential risks and complications exist with balloon sinus dilation. Possible side effects include but are not limited to post-operative bleeding; pain and swelling; tissue and mucosal trauma; optic injury;

voice changes; paired sense of taste or smell; nasal obstruction, dryness and pain; spinal fluid leak; allergic reaction to anesthesia or other medications administered during the procedure; or infection. Your condition may not respond to this treatment.

The risks to the embryo, fetus, or infant from the study procedure are unknown. Pregnant women must not participate in this study.

Benefits:
An expected benefit from the Sinusway endoscope is a direct visual look into the sinus cavities and tissue allowing better assessment, with minimal removal of healthy tissue. The Sinusway endoscope is an investigational device and therefore no benefit can be guaranteed at this stage. The results of this study may benefit patients in the future.

Alternative Treatment:
In any case the surgeon will use a standard endoscope during your surgery. You can choose not to take part in this study and the surgeon will only use the standard endoscope used during your surgery.

Confidentiality:
Your name and personal information will remain confidential and will not be publicized in any manner whatsoever. You will not be able to be identified by your name or another recognizable way in files, results or publication related to this clinical trial. Your identity will be kept secret, as information about your person will be referred to on the basis of a unique patient-number (i.e, encoded).

In accordance with the guidelines of good clinical practice your medical file, in so far as it relates to the study, could be inspected by representatives of the sponsor 3NT Medical Ltd, WIRB and regulatory authorities (including the U.S. Food and Drug Administration) in order to verify the authenticity of the information gathered. Absolute confidentiality cannot be guaranteed because of the need to give information that might identify you to these parties.

The encoded research data can be redirected to other supervisory authorities, to the relevant ethics committees, to other physicians and / or organizations working with the sponsor.

Your consent for participation in this study implies also your consent to the use of your encrypted medical data for the information described in these document objectives and for transmitting it to the above persons and groups. The sponsor agrees to only use the data collected within the context of this research in which you participate.

If you withdraw your consent to participate in the study, the data that have been coded until the moment you withdrew will be kept coded until the end of the study to ensure the validity of research. No new data will be sent to the sponsor.

Voluntary:
Your participation in this study is entirely voluntary, and any refusal on your part to participate or continue with this study will not involve any penalty or loss of benefit to which you would be otherwise entitled. You may decide at any time to discontinue your participation in this study,

and any such decision will not involve any penalty or loss of benefit to which you would be otherwise entitled. New findings relevant to your willingness to participate in the study shall be made available to you in a timely manner.

Termination of subject participation:
Participation in the study may be terminated if the investigator decides that it is in the patient's best interest

Injury:
In the case of injury or illness that is a direct result from participating in this study, emergency medical treatment will be provided.

Full medical insurance policy has been purchased to cover the Patient, Doctors and Hospital for any event that might occur as a direct result from participating in this study.

Costs associated with your participation to the trial:
3NT Medical Ltd. is the sponsor and will pay all costs for this research. The sponsor reimburses the hospital for the time spent by the researcher and his/her team to conduct the research, consultations specific to the study and for all planned tests and procedures for this study. Your decision to participate in this research will not result in additional costs to you or your health insurance. You will be charged with the cost corresponding to the usual medical care in your clinical situation only.

The sponsor has ensured that you get an adequate reimbursement for your travel expenses.
You get a total fee of $100 for your participation in the study. Contact the research team for the practical arrangements.

Financial Disclosure
Dr. Johnson owns stock in the sponsor company (3NT Medical). Please feel free to ask any further questions you might have about this matter.

Insurance:
Participation in a clinical trial involves a risk, however small that may be. Even if there is no fault, the sponsor accepts responsibility for injury to participants (or in case of death, his/her dependents) which are directly or indirectly related to his/her participation in the study. The sponsor has purchased an insurance policy to cover this responsibility.

We therefore ask you to always report new problems with your health to the investigator. He/she will be able to give you more information about possible treatments. If the investigator finds that there is a possible link with the research (the insurance does not cover the natural course of your disease or known side effects of your normal treatment), he/she will notify the sponsor of the study. The sponsor will then start administrative procedure before the insurance company, which will appoint an expert – if deemed necessary - that must judge whether there is a connection between your new health problems and the research. If you disagree with the investigator appointed by the insurance company expert and whenever you think it is appropriate, you or - in case of death – your survivors can start proceedings against the insurer itself at Howden UK Group Limited.

Ethical commission:
An independent ethics committee, namely Western Institutional Review Board, will monitor the study (Email address: Help@wirb.com). It is the task of the ethics committee to protect the rights and welfare of people who participate in a clinical trial. .

Contact:
If you have any questions, concerns, or complaints about this research or any aspect of your participation in this study, your rights, or your available options in the event of a research related injury; you may contact your doctor or the Principal Investigator (PI)

Jacob Johnson, MD at 801-475-3000 (24 Hours)

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

By signing this consent form, you are ascertaining that the investigators have answered all your questions to the best of their ability. If you have any other questions in the future regarding this study, the investigators will answer them to the best of their ability.

Copy:
After signing this consent form, you will receive a copy for your records.

Your signature below indicates that you have read the above information describing the investigation (or it has been read to you), and you understand the information you have received and that Dr. Jacob Johnson has answered any questions you have at this time.

The sponsor reserves the right to postpone or cancel this investigation and to remove you as a participant in the study.

Informed Consent Form

Patient Number: _____

Patient Initials: _____

Title of the Study: Safety and Effectiveness Evaluation of the Sinusway™ Device for Endoscopy of the Nasal Cavity and Paranasal Sinuses in Conjunction with Sinus Balloon Dilation

***Section, which is only for the patient*:**

I, undersigned, hereby confirm that I have been informed about the study and that I have received a copy of the "Patient Information Sheet" and the "Consent Form".

I have read the information provided. I have understood the meaning of this information and I have been able to ask any questions I found necessary.

My doctor has given me sufficient information concerning the conditions and the length of the study and the effect and the side effects of this treatment. I have received and understood the following information:

- The purpose of this study is to assess the safety and effectiveness of the Sinusway Device for Endoscopy – an endoscope used in the nasal cavity and paranasal sinuses.
- I have received a copy of the patient information form and the informed consent form.
- I have understood that my participation is voluntary and I have understood that I can end my participation in this study at any time after having informed my doctor about this and that this decision will not cause me any disadvantage.
- I confirm that I have had the opportunity to study the information provided to me in regards to this study, and to ask questions which were answered satisfactorily by the study doctors and/or their research staff.
- I understand that relevant sections of my medical records and data collected during this study may be looked at by regulatory bodies, the sponsor or its representative, and/or the Ethics Committee, as these records and data relate to my participation in this study. I give permission for these individuals to have access to my records.
- I agree to take part in the above-mentioned study and to comply strictly with the procedures and follow-up requirements of this study.
- I agree to the collection, the processing and the use of these medical data, as described in the patient information sheet. I also agree to the transfer and the processing of these data in countries other than United States.
- I agree to the use by the sponsor of these coded medical data for other research purposes.
- I agree to my GP/specialist and other healthcare professionals involved in my treatment being informed about my participation in this study.

Name of Patient	Signature	Date

Doctor's declaration:
I, undersigned, hereby confirm that I have provided information on the study to the above-mentioned patient and that he/she has consented to participate in the study.

Name of Investigator	Signature	Date