Prospective European post-marketing study to confirm Efficacy and Safety of carticol®

Study Participant Information

Dear study participant,

We would like to ask you if you are willing to participate in the clinical trial described below.

The study is performed in Germany and the Netherlands on the Internet. There is a total number of 300 people to participate. The study is initiated, organised and financed by the Ten Kate Health Supplements B.V., Musselkanaal, Groningen, The Netherlands.

Your participation is voluntary. You only will be included if you declare your consent in writing. You may withdraw your consent at any time without giving reasons and without consequences.

1 Aim of the clinical trial; interests of the initiator

The main aim of this study is the evaluation of efficacy and safety of carticol®. This is a dietary supplement that, in addition to undenatured collagen type II (T2NDC®), contains some vitamins (C, D and E), hyaluronic acid, methylsulfonylmethane (MSM) and manganese.

The study investigates, if the study product decreases the symptoms of knee osteoarthritis and ameliorates.

2 What kind of disease is it about?

Knee osteoarthritis, which you are suffering from, is a disease of degradation / degeneration of the articular cartilage. All non-operative forms of therapy of osteoarthritis try to reduce the progress of degradation and to decrease the pain that may occur.

The nutritional supplement investigated here does not claim to replace standard drug therapy.

3 Who may participate in the study?

People older than 30 years suffering from Knee osteoarthritis.

There are some criteria, called exclusion criteria, that make participation in this clinical trial impossible :

- You are suffering from rheumatoid arthritis
- You are pregnant or lactating
- You have participated in another clinical investigation during the last 3 months
- You have an allergy to any of the product ingredients :
  methylsulfonylmethane (MSM), ascorbic acid, capsule shell (coating agent hydroxypropylmethylcellulose, thickener gellan), poultry collagen, vitamin E (D-alpha-tocopheryl acetate, carrier silica), hyaluronic acid, manganese bisglycinate, cholecalciferol, release agent magnesium stearate, maltodextrin, and gelatin

If none of these apply, you can participate in the study.

4 Benefits and risks of participating in this study

You are contributing to research about the efficacy of carticol® for knee osteoarthritis.

The study product contains some vitamins and MSM in sufficient doses. Two capsules already contain the daily requirement of vitamins C, D and E. Therefore, the recommended daily intake of the study product must not be exceeded and no additional preparations containing vitamins C, D and E must be taken.

If during the course of the study new findings become known that could affect your decision to continue participating in this study, you will be informed immediately.

5 Study groups

In this study, three groups of participants will be compared with each other. Therefore, the participants will be divided by lot in three groups.

Group A receives carticol®
Group B placebo, i.e. without collagen
Group C undenatured type II collagen alone

Which group you are assigned to is defined by a random procedure. Neither you nor the manufacturer knows, which group you will belong to (double-blind study), i.e. whether you are receiving carticol® or not.

6 Procedure of the study

On the Internet, please go to www.carticol-study.eu to go to a specific page of Aix Scientifics® in the web. On this website, some questions are followed by a request regarding your personal address data and a preliminary consent to the study.

After submitting your data, you will receive an SMS for access to the study questionnaire, so that you can log into the questionnaire via smartphone or computer on the Internet.

Please fill-in this questionnaire about the health of your knee. Finally, you will be asked to download the study participant information and print out the signature page. Please read these pages carefully.

After completing the questionnaire, we ask you to contact Aix Scientifics® by phone (+49 241 4500 358) before signing your participation in the study. With your signature you formally declare your participation in the study and you agree to take 2 capsules of the study product daily for 16 weeks. You are also ready to answer the same questionnaire every 4 weeks on the Internet. You can do that on your computer or smartphone.

Please send your participation signature page to :

Aix Scientifics® , Theaterstr. 7, 52062 Aachen, Germany

or scan / take a picture of the document and send it by e-mail to :

carticol@aix-scientifics.com

As a study participant, you will receive the allotted study product from the manufacturer free of charge.

As described above, at the start of the clinical trial and then for 4 months, you will be asked to fill out the knee health questionnaire every month.

7 Do I have to pay for my participation in the study ?

Apart from the postage for a letter, you will not incur any costs for participating in this study. However, you will not receive any expenses. The study material will be sent to you free of charge.

Note: since the study product is on the market, no study-specific insurance is provided.

8 Can my participation in the study be terminated untimely ?

You can withdraw your participation at any time, without giving reasons and without incurring any disadvantages.

9 Who do I contact if I have further questions ?

If you have any questions regarding the study product, please contact the manufacturer and initiator of the study :

Ten Kate Health Supplements B.V.
CEO: Dr. Ludwig Decker
Sluisstraat 56 , 9581 JC Musselkanaal, Groningen, The Netherlands
tel.: +31 599 412 605
e-mail : protein@tenkate.nl

10a What happens to my data ?

(Information on data protection in accordance with Art. 13 ff EU General Data Protection Regulation - GDPR)

Within the clinical study personal data are recorded and transmitted to Aix Scientifics®. Aside from identifying data (full name, year of birth, address, e-mail address and smartphone number), it includes study data (like age, height and weight, as well as data for evaluating the disease in the KOOS questionnaire). The participation signature page are identifying data too.

In order to send the study product, the manufacturer receives the name and address of the study participant; the manufacturer does not receive any further identifying data, not even which study group the participant belongs to (the study packages had been coded by Aix Scientifics® in advance). All identifying data will be deleted 10 years after the study is completed.

The study data (see above) are electronically stored and evaluated in pseudonymised form with the help of a study-specific consecutive participant number (o001, o002, o003, etc.), i.e. without direct access to the identifying data. Until the deletion of the identifying data, an allocation to a person is only possible with the help of the allocation list, which (like the identifying data except name and address) remains with Aix Scientifics®.

The pseudonymised study data in the narrow sense (see above) and their evaluation will be handed over to the manufacturer at the end of the study.

May be, an authorised representative of the study initiator or an inspector of the government who is bound to secrecy will inspect the study data and may become aware of your personal data, insofar as this is necessary for the review of the study.

10b Where are my data collected and stored ?

The data is recorded on the Internet using the data acquisition system from Aix Scientifics®. The transmission takes place via SSL/TLS-encrypted websites. The Internet server as well as the backup server is in Germany. If you have any further questions regarding the study, please contact:

Contract Research Organisation : **Aix Scientifics®**
Dr. Eike G. Fischer
Theaterstr. 7, 52062 Aachen, Germany
tel.: +49 241 4500 358
e-mail : eike@Aix-Scientifics.com

Physician: **Karsten Schmidt**
e-mail : mail@Karsten-Schmidt.eu

Data safety officer: **Sebastianus Sutanto**
e-mail : safetyofficer@Aix-Scientifics.com

10c legal basis for processing your data

The legal basis for the collection and processing of your personal data is your consent to participate in the study in accordance with article 6 paragraph 1 lit. a General Data Protection Regulation (GDPR) and article 9 paragraph 2 lit.a.

You have the right to revoke your data protection consent at any time. By withdrawing your consent the legality of the processing the data carried out on the basis of the consent is not affected until the revocation. (Revocation with effect for the future). Please send the revocation to Aix Scientifics® (see address above).

After receipt of the revocation, your further participation in the study will be terminated. There are no disadvantages for you through the revocation.

According to article 13 paragraph 2 lit.b of the GDPR you have the following right :

Data access by the data subject (article 15 GDPR and Section 34 BDSG)
Objection (article. 21 GDPR and Section 36 BDSG)
Data portability (article 20 GDPR)
Erasure ('right to be forgotten') (article 17 GDPR and Section 35 BDSG)
Restriction of processing (article 18 GDPR)
Rectification (article 16 GDPR)

To enforcement of rights mentioned, please contact Aix Scientifics®.

You also have the right to file a complaint with the regulatory authority. You can find an overview of the responsible competent authorities under the following link:
https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human

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Informed Consent

.....
Name of the study participant in block letters

Born on ..... Study participant number.....

I have read and understood the foregoing information including the information on data protection. There was the possibility to ask my questions over the phone. I had enough time to make up my mind.

I am aware that I can withdraw my consent to participate in the study any time without giving any reason and without incurring any disadvantages.

I hereby consent voluntarily to the collection and processing of my personal data. I have been informed about the consequences of withdrawing consent of the data protection law.

I voluntarily agree to participate in the above study

I will keep a copy of the participant information and this informed consent.

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Signature of participant Date