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The effect of food on the proportion of chondroitin sulfate that enters the blood after Condrosulf® tablets are taken in healthy male and female volunteers

Submission date
30/05/2022

Recruitment status
No longer recruiting

Registration date
03/06/2022

Overall study status
Completed

Last Edited
01/02/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chondroitin sulfate is a substance found naturally in the human body. It is taken as a supplement for joint problems. This study aimed to investigate the bioavailability (how much of a substance enters the bloodstream) and pharmacokinetics (the way a substance medicine moves inside the body) of chondroitin sulfate after healthy volunteers took Condrosulf® tablets containing chondroitin sulfate and also to investigate whether the tablets had any side effects.

Who can participate?
Healthy men and women aged 30-65 years inclusive

What does the study involve?
Participants received a single 1600 mg dose of chondroitin sulfate tablets on two separate days, once after they had eaten no breakfast and once after they had eaten a substantial breakfast. Blood was taken at intervals before and after the tablets were taken.

What are the possible benefits and risks of participating?
Chondroitin sulfate is widely used and is considered safe. No potential risks were foreseen for the subjects enrolled in the present study. In previous clinical studies, the most common side effects involved the gut, i.e. indigestion and abdominal pain, and the nervous system, i.e. headache (which occurred in less than 10% of patients). Nausea, constipation, dizziness and skin disorders (rashes) occurred in less than 1% of patients. However, as with all products, the appearance of known or not yet known allergic reactions or side effects couldn't be ruled out. No potential benefits were foreseen to volunteers participating to the current study with the exception of the medical tests that were performed during it.

Where is the study run from?
CROSS Research S.A. Phase I Unit Clinical Centre (Switzerland)

When is the study starting and how long is it expected to run for?
February 2020 to June 2021

Who is funding the study?
IBSA Institut Biochimique SA, Switzerland

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
20CH-Ct04, CRO-PK-21-351

Study information

Scientific Title
Food effect study of Condrosulf® chondroitin sulfate tablets in healthy male and female volunteers

Study objectives
The objective of the study was to investigate the effect of food on the bioavailability of total chondroitin sulfate* after single dose of Condrosulf®, administered under fed and fasting conditions to healthy male and female subjects.
*Note: chondroitin sulfate was calculated as the sum of ΔDi-4S, ΔDi-0S, ΔDi-6S disaccharides

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/04/2021, Canton Ticino Ethics Committee (c/o Ufficio di sanità, Via Orico 5, 6501 Bellinzona, Switzerland; +41(0)91 814 30 57; michaela.gutacker@ti.ch), ref: 2021-00716 / CE 3854

Primary study design
Interventional

Study design
Single-dose, single-center, open-label, randomized, two-way, cross-over, food effect study

Study type(s)
Other

Health condition(s) or problem(s) studied
Food effect study in healthy volunteers

Interventions
Investigational product: Condrosulf®, chondroitin sulfate 800 mg tablets, IBSA Institut Biochimique SA, Switzerland.
A single 1600 mg dose of chondroitin sulfate tablet was administered in each of two consecutive

study periods, under fed and fasting conditions, according to a two-way cross-over randomized design. The investigational product was administered as two 800 mg tablets to be taken consecutively with 240 ml of still mineral water. A wash-out interval of at least 7 days elapsed between the consecutive administrations. Subjects allocated to treatment under fed conditions were provided with a standardized high-fat high-caloric breakfast 30 min pre-dose. They had to completely eat their breakfast within 30 min and before investigational product administration. Subjects allocated to treatment under fasting conditions didn't receive any food before administration.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Condrosulf® (chondroitin sulfate 800 mg tablets)

Primary outcome(s)
Chondroitin sulfate Cmax, AUC0-t and AUC0-∞ calculated from levels measured using a fully validated analytical LC-MS/MS method in blood collected on Day -2 and Day -1 at 8:00 ±1 h, 13:00 ±1 h, 20:00 ±1 h and on Days 1, 2 and 3 at 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36 and 48 h post-dose

Key secondary outcome(s)
1. Chondroitin sulfate tmax, t1/2, λz, Cl/F and Vd/F calculated from levels measured using a fully validated analytical LC-MS/MS method in blood collected on Day -2 and Day -1 at 8:00 ±1 h, 13:00 ±1 h, 20:00 ±1 h and on Days 1, 2 and 3 at 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36 and 48 h post-dose
2. ΔDi-4S, ΔDi-0S, ΔDi-6S disaccharides bioavailability calculated from levels measured using a fully validated analytical LC-MS/MS method in blood collected on Day -2 and Day -1 at 8:00 ±1 h, 13:00 ±1 h, 20:00 ±1 h and on Days 1, 2 and 3 at 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 12, 24, 36 and 48 h post-dose
3. Safety and tolerability assessed using treatment-emergent adverse events recorded throughout the study duration
4. Blood pressure measured by the Investigator or his deputy after 5 min at rest (in sitting position) using a manual sphygmomanometer at the screening visit, at Day 1 of each period pre-dose and 3 h post-dose, Day 2 of each period 24 h post-dose, Day 3 of each period 48 h post-dose and at the early termination visit (if applicable)
5. Heart rate measured by the Investigator or his deputy after 5 min at rest (in sitting position) using a manual sphygmomanometer at the screening visit, at Day 1 of each period pre-dose and 3 h post-dose, Day 2 of each period 24 h post-dose, Day 3 of each period 48 h post-dose and at the early termination visit (if applicable)
6. Electrocardiographic evaluation and ECG parameters measured using 12-lead ECG performed in supine position at screening and final visit/early termination visit
7. Body weight measured using a professional personal floor scale at screening and final visit /early termination visit
8. Height measured using a stadiometer at screening
9. A standard panel of haematological and urinary parameters measured using laboratory testing on blood and urine samples collected at screening and final visit/early termination visit

Completion date
14/06/2021

Eligibility

Key inclusion criteria
1. Signed written informed consent before inclusion in the study
2. Men and women aged 30-65 years inclusive
3. Body mass index (BMI) of 18.5-30 kg/m2 inclusive
4. Systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, heart rate 50-90 bpm, measured after 5 min at rest in the sitting position
5. Ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the Investigator and to comply with the requirements of the entire study
6. Contraception and fertility (women only): women of child-bearing potential must be using at least one of the following reliable methods of contraception:
6.1. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit
6.2. A non-hormonal intrauterine device or female condom with spermicide or contraceptive sponge with spermicide or diaphragm with spermicide or cervical cap with spermicide for at least 2 months before the screening visit
6.3. A male sexual partner who agrees to use a male condom with spermicide
6.4. A sterile sexual partner
7. Women of non-child-bearing potential or in post-menopausal status for at least 1 year will be admitted. For all women, pregnancy test result must be negative at screening.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
30 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
17

Key exclusion criteria
1. Electrocardiogram (ECG 12-leads, supine position) shows clinically significant abnormalities
2. Clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Clinically significant abnormal laboratory values indicative of physical illness
4. Ascertained or presumptive hypersensitivity to the active principle (chondroitin sulfate) and

/or formulations' ingredients or history of anaphylaxis to drugs or allergic reactions in general, which the Investigator considers may affect the outcome of the study
5. Significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, hematological, endocrine or neurological diseases that may interfere with the aim of the study
6. Medications, including over-the-counter medications, herbal remedies and food supplements containing chondroitin sulfate for 2 weeks before the start of the study. Hormonal contraceptives for females will be allowed.
7. Participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study.
8. Blood donations for 3 months before this study
9. History of drug, alcohol (>1 drink/day for females and >2 drinks/day for males, defined according to the USDA Dietary Guidelines 2020-2025), caffeine (>5 cups coffee/tea/day) or tobacco abuse (10 cigarettes/day)
10. Positive result in drug test at screening or Day -3
11. Positive alcohol breath test at Day -3
12. Abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before this study or vegetarians;
13. Pregnancy (women only): positive or missing pregnancy test at screening or Day -3 or pregnant or lactating women

Date of first enrolment
25/05/2021

Date of final enrolment
29/05/2021

Locations

Countries of recruitment
Italy

Switzerland

Study participating centre
CROSS Research S.A., Phase I Unit
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Sponsor information

Organisation
IBSA Institut Biochimique (Switzerland)

ROR
https://ror.org/051tj3a26

Funder(s)

Funder type
Industry

Funder Name
IBSA Institut Biochimique S.A.

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version 2022	22/11/2022	25/11/2022	No	No