Assessment of elemental impurities level after chronic administration of Diosmectite (SMECTA®) in subjects with chronic diarrhoea.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43250

Source
ToetsingOnline

Brief title
Metal traces after 5 weeks of Smecta® treatment.

Condition

- Other condition

Synonym
chronic diarrhea

Health condition

chronische diarree.

Research involving

Human

Sponsors and support

Primary sponsor: Ipsen Pharma SAS
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: chronic diarrhea, Diosmectite (Smecta®)

Outcome measures

Primary outcome

To assess the concentration of lead in blood, one of the Class I impurities defined by ICH Q3D guidelines, after chronic administration of Smecta® in subjects with chronic functional diarrhoea.

Secondary outcome

* To assess blood concentration of other Class I and IIa elemental impurities of interest (i.e. arsenic, cadmium, mercury, cobalt, vanadium, nickel and barium) and of aluminium after chronic administration of Smecta® in subjects with chronic functional diarrhoea;

* To assess urinary lead levels and urinary levels of other selected Class I and IIa elemental impurities of interest (i.e. arsenic, cadmium, mercury, cobalt, vanadium, nickel and barium), and aluminium after chronic administration of Smecta®;

* To further assess the safety and tolerance of Smecta® after chronic administration.

Study description

Background summary

Diosmectite is a drug that is used in children and adults in the treatment of acute diarrhea. Furthermore, it is used in adults in the treatment of chronic diarrhea or pain associated with functional bowel disorders. Diosmectite is a natural clay that helps repair intestinal damage with its natural coating properties. Diosmectite is extracted from special geological deposits and then cleaned and purified according to standards for medicinal use. Diosmectite is not a new drug; it is already available in the market in more than 70 countries for more than 40 years. In the current study, diosmectite will be provided as Smecta® oral solution with orange-vanilla flavor. Traces of metals can be present in Smecta® as they are natural components of clay. Recent International guidelines are limiting the amount of metals that can be traced in drug products. It is, however, unknown how much of these metal traces could be absorbed by the body when Smecta® is taken for a long period of time by patients with chronic diarrhea.

Study objective

The primary purpose of the study is to investigate how quickly and to what extent traces of metals that are naturally present in Smecta® could be absorbed and eliminated from the body (this is called pharmacokinetics). For exploratory purposes, the potential effects of Smecta® on the microbe population living in the intestine (formally called gut flora), will be investigated in feces before, during and after the chronic administration of Smecta®.

Study design

The actual study will consist of one treatment period of 35 days (5 weeks). Day 1 (Visit 2) is the first day of administration of the study compound. First, the volunteers will stay for one period of 3 days (2 nights; from Day -1 to Day 2) in the clinical research center in Groningen (location Martini Hospital). The day before first administration of the study compound they are expected in the clinical research center at 07:00 in the morning*. During the treatment period they will return to the clinical research center for 4 short visits (at 11:00 in the morning on Days 8, 15, 22 and 29 [Visits 3 to 6]) during which theu will take their dose at noon, and one stay in the clinical research center from Day 35 to Day 36 (location Martini Hospital). For this stay in the clinical research center they are expected at 07:00 in the morning of Day 35* and they will leave the clinical research center after completion of the assessments in the morning of Day 36.

Thereafter the volunteers will return for 3 post-study screenings (Visit 7 to 9) in the clinical research center in Groningen (location Martini Hospital), once a month for 3 months. These include one stay in the clinical research center from Day 65 to Day 66, another stay from Day 95 to Day 96, and a final short visit on Day 125 (± 7 days). For the stays on Day 65 and Day 95 they are expected in the clinical research center at 07:00 in the morning*. They will be discharged from the study after completion of the last visit (Day 125, Visit 10) for follow-up assessments. The appointment for Day 125 will be made when they are in the clinical research center. * For the admissions at 07:00 in the morning of Day -1, Day 35, Day 65 and Day 95, there may be an option to enter the clinical research center at 20:30 in the evening before these days (Day -2, Day 34, Day 64 and Day 94, respectively). These options and any consequences for the remuneration will be discussed with the volunteers before admission. The participation to the entire study, from the pre-study screening until the post-study screening, will be approximately 5.5 months.

Intervention

Diosmectite (Smecta® 3g/sachet, powder for oral suspension. Three sachets per day (TID). (morning, noon, and evening).
For the purpose of this study, Smecta® should be taken fasting and at least one hour before meal, except for breakfast at least * hour before.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

male or female patients with chronic diarrhea
18 - 60 years of age, inclusive
BMI 19 - 32 kilograms/meter2
non smokers

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	35
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Smecta®
Generic name:	n.a.
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	27-07-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	19-08-2016
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	04-10-2016
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-002111-18-NL
CCMO	NL58669.056.16