TREATMENT WITH BISMUTE SUBCITRATE IN FRAGILE PATIENTS WITH SARS-CoV-2 INFECTION AND DIARRHEA NOT FITTING FOR TRANSFER TO ACUTE HOSPITAL (COVID-19) (COVID-19 BISMUTE)

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Study Planned

Administrative details

EU PAS number

EUPAS34925

Study ID

34990

DARWIN EU® study

No

Study countries

☐ Spain

Study description

In the course of the current pandemic caused by the spread and replication of SARS-Cov-2, respiratory symptoms dominate the clinical picture of the disease. However, a significant percentage of patients with COVID-19 infection present with gastrointestinal symptoms, such as anorexia, vomiting, diarrhea and abdominal pain, which are not always associated with respiratory symptoms or clinics. This percentage, according to current medical literature, ranges from 34% to 60%. Our study wants to focus basically on patients whose main symptom is diarrhea and because of their characteristics of fragility and associated comorbidities are not candidates for referral to acute hospital or aggressive therapies. Bismuth colloidal compounds such as bismuth subsalicylate are antidiarrheal drugs whose mechanism of action is combined: on the one hand, it stimulates the absorption of fluids and electrolytes through the intestinal wall by inhibiting the secretion of chloride, and on the other hand, when hydrolyzed to salicylic acid, it inhibits the synthesis of prostaglandins responsible for intestinal inflammation and hypermotility. Its action is anti-secretory and antimicrobial.In the context of the SARS-CoV-2 infection pandemic, a prioritization of the use of health resources is established. This implies that frail, elderly patients with chronic diseases who, in addition, are often admitted to centres with a high incidence of COVID-19, do not have access to mechanical ventilation, and therefore have even higher mortality. Diarrhea is a major problem in these patients so we have designed a prospective study in which the main objective is to determine the efficacy of bismuth subcitrate treatment in COVID-19 patients with acute diarrhea.Main objective:To determine the efficacy of bismuth subcitrate in the treatment of diarrhea as the main symptom of COVID 19 disease, in the group of fragile patients with associated comorbidities and not candidates for invasive therapy

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Study status

Planned

Research institutions and networks

Institutions

Hospital Sociosanitario Francolí

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eugenia Sopena

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2020

Actual: 15/04/2020

Study start date

Planned: 04/05/2020

Data analysis start date
Planned: 05/10/2020

Date of interim report, if expected
Planned: 17/12/2020

Date of final study report
Planned: 15/01/2021

Sources of funding

- Other

More details on funding

Internal Funding

Study protocol

Bismuth. English.pdf(132.1 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To determine the efficacy of bismuth subcitrate in the treatment of diarrhea as the main symptom of COVID 19 disease, in the group of fragile patients with associated comorbidities and not candidates for invasive therapy or acute hospital referral.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Self-controlled case series

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(A07) ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS

Medical condition to be studied

COVID-19 treatment

Population studied

Age groups

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

32

Study design details

Data analysis plan

Main endpoint: To determine the efficacy of bismuth colloidal compounds in fragile and pluripathological patients, with diagnosis of VIDOC19 and presence of diarrhea. The number of diarrheal stools per day and the number of days with stools will be analyzed.Secondary endpoint: To analyze if the concomitant pathology influences the evolution of the patient, through the calculation of the Charlson Index.Analysis of the results: Quantitative variables will be described by means and standard deviation (if they follow a normal distribution) or by median and range. Qualitative variables will be described by percentages and 95% confidence intervals.

Documents

Study publications

Holshue ML, DeBolt C, Lindquist S, Lofy KH, Wiesman J, Bruce H, Spitters C, Eri…

Song Y, Liu P, Shi XL, Chu YL, Zhang J, Xia J, Gao XZ, Qu T, Wang MY. SARS-CoV-…

Daghaghzadeh H, Memar A, Mohamadi Y, Rezakhani N, Safazadeh P, Aghaha S, Adibi …

Data management

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

conflict interest.pdf(76.28 KB)

Composition of steering group and observers

steering bismuth.pdf(65.17 KB)

Signed code of conduct

empty-file.pdf(14.94 KB)

Signed code of conduct checklist

empty-file.pdf(14.94 KB)

Signed checklist for study protocols

empty-file.pdf(14.94 KB)

Data sources

Data sources (types)

Drug dispensing/prescription data

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No