Efficacy and Safety of Calcifediol vs Placebo in Subjects With Vitamin D Deficiency (WORFEROL)

ClinicalTrials.gov Identifier: NCT04735926

Recruitment Status : Recruiting
First Posted : February 3, 2021
Last Update Posted : March 3, 2021

See Contacts and Locations

Sponsor:
Faes Farma, S.A.

Information provided by (Responsible Party):
Faes Farma, S.A.

Study Description

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Brief Summary:
This is a randomised, double-blind, double-dummy, multicentre, dose-ranging clinical trial in subjects with vitamin D deficiency or insufficiency. Its general objective is to determine the efficacy and safety of different doses of calcifediol soft gelatin capsules (SGCs) compared to placebo.

Condition or disease	Intervention/treatment	Phase
Vitamin D Deficiency Vitamin D Insufficiency	Drug: Calcifediol 75mcg Drug: Calcifediol 100mcg Drug: Calcifediol 125mcg Other: Placebo	Phase 2 Phase 3

Study Design

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Study Type :
Interventional (Clinical Trial)

Estimated Enrollment :
795 participants

Allocation:
Randomized

Intervention Model:
Parallel Assignment

Masking:
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose:
Treatment

Official Title:
Randomised, Double-blind, Double-dummy, Multicentre Trial to Evaluate the Efficacy and Safety of Three Different Weekly Dosages of Calcifediol Versus Placebo in Subjects With Either Vitamin D Deficiency or Insufficiency.

Actual Study Start Date :
December 23, 2020

Estimated Primary Completion Date :

November 30, 2021

Estimated Study Completion Date :

July 31, 2022

Resource links provided by the National Library of Medicine

MedlinePlus related topics: Vitamin D Vitamin D Deficiency

Drug Information available for: Calcifediol

U.S. FDA Resources

Arms and Interventions

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Arm	Intervention/treatment
Placebo Comparator: Group 1A Subjects corresponding to Cohort 1 (25-OH-D baseline level > 10 to < 20 ng/mL)	Other: Placebo Soft gelatin capsule. Oral administration once per week.
Experimental: Group 1B Subjects corresponding to Cohort 1 (25-OH-D baseline level > 10 to < 20 ng/mL)	Drug: Calcifediol 75mcg Soft gelatin capsule. Oral administration once per week Other: Placebo Soft gelatin capsule. Oral administration once per week.
Experimental: Group 1C Subjects corresponding to Cohort 1 (25-OH-D baseline level > 10 to < 20 ng/mL)	Drug: Calcifediol 100mcg Soft gelatin capsule. Oral administration once per week Other: Placebo Soft gelatin capsule. Oral administration once per week.

Arm	Intervention/treatment
Placebo Comparator: Group 2A Subjects corresponding to Cohort 2 (25-OH-D baseline level ≤ 10 ng/mL)	Other: Placebo Soft gelatin capsule. Oral administration once per week.
Experimental: Group 2B Subjects corresponding to Cohort 2 (25-OH-D baseline level ≤ 10 ng/mL)	Drug: Calcifediol 100mcg Soft gelatin capsule. Oral administration once per week Other: Placebo Soft gelatin capsule. Oral administration once per week.
Experimental: Group 2C Subjects corresponding to Cohort 2 (25-OH-D baseline level ≤ 10 ng/mL)	Drug: Calcifediol 125mcg Soft gelatin capsule. Oral administration once per week. Other: Placebo Soft gelatin capsule. Oral administration once per week.

Outcome Measures

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Primary Outcome Measures :

1. To assess efficacy for each cohort in terms of percentage of subjects achieving 25-OH-D levels ≥ 30 ng/mL and/or ≥ 20 ng/mL at 16 weeks of treatment. [Time Frame: 16 weeks]

   Percentage of subjects who achieve 25-OH-D levels ≥ 30 ng/mL and/or ≥ 20 ng/mL

Eligibility Criteria

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Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years to 65 Years (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

Yes

Criteria

Inclusion Criteria:

- Male or female subjects ≥ 18 years of age.
- Evidence of serum 25-OH-D levels < 20 ng/mL or ≤ 10 ng/mL, for each cohort.
- Written informed consent.
- For females of childbearing potential only: willing to perform pregnancy tests, must agree to use highly effective methods of birth control throughout the study.

Exclusion Criteria:

- Subjects receiving any treatment with calcifediol, vitamin D analogues, vitamin complexes or vitamin D supplements.
- Subjects taking drugs that could modify vitamin D levels.
- Subjects taking calcium supplements.
- Uncorrected hypercalcaemia, known hypercalciuria or nephrolithiasis.
- Severe renal impairment.
- Subjects diagnosed with liver or biliary failure, congestive heart failure, malabsorption, primary hyperparathyroidism, hypothyroidism, prolonged immobilisation, sarcoidosis, tuberculosis or other granulomatous diseases or hyperthyroidism.
- Any present or previous malignancy.
- Known contraindications or sensitivities to the use of the IP or any of its components.
- Pregnant woman, breastfeeding woman or woman planning a pregnancy.
- Subject has received an IP within 30 days before the start of the screening or is currently enrolled in an investigational interventional study.
- Any condition that may jeopardise the clinical trial conduct according to the protocol.

- Employees of the investigator or clinical trial site, as well as family members of the employees or the principal investigator.
- Person committed to an institution by virtue of an order issued either by judicial or other authorities.

Contacts and Locations

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Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04735926***

Contacts

Contact: Nieves Fernández +34 670256227 nfernandez@faes.es

Locations

Show 59 study locations

Sponsors and Collaborators

Faes Farma, S.A.

More Information

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Responsible Party:
Faes Farma, S.A.

ClinicalTrials.gov Identifier:
NCT04735926 History of Changes

Other Study ID Numbers:
HIDR-0320/DR

First Posted:
February 3, 2021 Key Record Dates

Last Update Posted:
March 3, 2021

Last Verified:

January 2021

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:

No

Studies a U.S. FDA-regulated Drug Product:

No

Studies a U.S. FDA-regulated Device Product:

No

Additional relevant MeSH terms:

Vitamin D Deficiency
Avitaminosis
Deficiency Diseases
Malnutrition
Nutrition Disorders
Calcifediol
Vitamins
Micronutrients
Nutrients
Growth Substances
Physiological Effects of Drugs
Bone Density Conservation Agents