A Single-Center, Single-Cohort Study of FF-37101 for Bone Formation in the Maxillomandibular Region

Gepubliceerd: 07-02-2020 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24676

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Reduction of Jawbone

Ondersteuning

Primaire sponsor: Fujifilm Manufacturing Europe BV
Overige ondersteuning: Company

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary performance endpoint: The proportion of patients that has bone formation assessed based on bone height measurements, in the grafted site after 6 months, as identified by CBCT imaging.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a single center, single cohort, non-randomized, open label clinical study to demonstrate the performance and safety of FF-37101, intended to support new bone formation in the maxillomandibular region. The study will target to implant 30 subjects with FF-37101 in order to follow at least 23 subjects for 6 months post-treatment.

Doel van het onderzoek

A one-sided exact binominal test of proportions will be used to determine if the proportion of patients (π) that have bone formation assessed based on bone height measurements, in the grafted site after 6 months, as identified by CBCT imaging, will be greater than 50%. If the p-value from this test is less than or equal to 0.05 then we will state that there is significant evidence to reject the null hypothesis that the proportion is less than or equal to 50% in favor of the alternative that the proportion is greater than 50%.

Onderzoeksopzet

0, 1 week, 2 weeks, 1 month, 2 months (phone contact), 3 months, 6 months

Onderzoeksproduct en/of interventie

Use of FF-37101 as bone graft scaffold after tooth extraction

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization.
• 18 year or older at time of informed consent.
• Have 1 tooth (front, pre-molar or molar) of poor prognosis diagnosed for tooth extraction.
• Have 1 or more healthy tooth/teeth immediately adjacent to the tooth that is to be extracted.
• Have a type I or type II socket of the buccal alveolar bone of the tooth to be extracted.
• Absence of pockets of 5mm or more in the full dentition, with exception of the pocket of the tooth to be extracted.
• Able to return for follow-up visits, as defined in this clinical investigation plan, after tooth extraction.
• Scheduled to have an implant placed 6 months after tooth extraction and FF-37101 implantation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Signs of active inflammation, i.e. presence of inflammatory fluid during tooth extraction.
• Active generalized periodontal disease; evident periapical radiolucencies or abscesses; autoimmune disorders; taking or having a history of bisphosphonate medications or Denosumab (history of MRONJ (medication-related osteonecrosis of the jaw)/BRONJ (bisphosphonate-related osteonecrosis of the jaw)); congenital or metabolic bone disorders; or uncontrolled diabetes.
• Full coverage restoration or large metallic restoration work including dental implant completed on any tooth adjacent to the tooth to be extracted in this clinical investigation.
• Current or former smoker or user of chewing tobacco or nicotine-containing products. Former smokers or users are defined as subjects who smoked 10 cigarettes or more (or an equivalent amount of other tobacco products) per day in the 5 years prior to screening.
• Females who are pregnant, breastfeeding, or are planning to conceive during their enrollment in the clinical investigation.

• History of any clinically significant mental and/or psychological, or other major disease, as determined by the investigator that would prevent dental treatment.
• Inability to effectively communicate with study staff during the clinical investigation.
• History of any severe allergic or anaphylactic reactions to collagen or gelatin, or current sensitivity to collagen or gelatin.
• Unwillingness or inability to comply with the requirements of this clinical investigation plan.
• Previous head and neck radiation- or chemo-therapy.
• Other reasons that, in the opinion of the investigator, will make the subject unsuitable for enrollment.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	07-02-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55475
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8363
CCMO	NL65005.028.19
OMON	NL-OMON55475

Resultaten