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A single-center, blinded, placebo-controlled randomized study of the effect of CRX-150 on serum C-Reactive Protein (CRP) and inflammatory cytokines compared to placebo in subjects with severe adult periodontitis

Submission date 20/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 16/10/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/03/2017	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRx-150-001-01

Study information

Scientific Title
A single-center, blinded, placebo-controlled randomized study of the effect of CRX-150 on serum C-Reactive Protein (CRP) and inflammatory cytokines compared to placebo in subjects with severe adult periodontitis

Acronym
Perio-04-17

Study objectives
This study aims to assess the effect of CRx-150 (amoxapine and dipyridamole) on serum C-Reactive Protein (CRP) and inflammatory cytokines compared to placebo in adult with severe periodontitis. This is both the first study of the anti-inflammatory effects of CRx-150 in a subject population with a chronic inflammation, and also the first study of this combination in human.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College London Hospital Ethics Committee alpha, ref: 04/Q0505/58

Study design
Single-center blinded placebo-controlled randomized study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Periodontitis

Interventions
Daily CRx-150 (150 mg amoxapine and 200 mg dipridamole) administered orally or placebo for 8 weeks.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
CRx-150 (amoxapine and dipyridamole)

Primary outcome measure
Reduction in CRP levels in subjects with severe adult periodontitis treated with CRx-150 compared to placebo over the course of six weeks.

Secondary outcome measures
1. Changes in inflammatory cytokine profiles, measured at each visit, 10 visits in total during the intervention
2. Change in periodontal pocket depths between baseline and 8 weeks
3. Changes in CRP levels following SRP, measured between Visit 7 and 8

Overall study start date
01/09/2004

Completion date
01/03/2006

Eligibility

Key inclusion criteria
1. Subject must be between the ages of 18 and 70.
2. Subject must have severe periodontitis, defined as subjects with at least 10 pockets more than or equal to 5 mm in depth, with at least four pockets more than or equal to 6 mm. Ten percent (10%) of all pockets must bleed on probing. Subject must otherwise be in good general health.
3. Subject has a baseline C-reactive protein level of more than or equal to 1.5 mg/L.
4. Subject must have voluntarily signed the informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria

1. Female subject is pregnant or lactating or of child bearing potential not using acceptable methods of birth control (hormonal, barriers or abstinence).
2. Subject is currently taking any anti-depressants or anti-seizure medication.
3. Subject has a history of seizure disorders.
4. Subject has a history of asthma.
5. Subject had a myocardial infarction within six months of enrollment.
6. Subject has received periodontal treatment in the last three months, including Scaling and Root Planing (SRP), Arestin, Periochip, Atridox and/or Periostat.
7. Subject is currently taking a statin, and has not been on stable dosing for 6 months prior to entering into the trial.
8. Subject is on chronic treatment (i.e., two weeks or more) with any medication known to affect periodontal status (e.g., phenytoin, dihydropyridine calcium antagonists, cyclosporine, and non-steroidal anti-inflammatory drugs) within one month of baseline visit.
9. Subject is on concomitant therapy of warfarin (coumadine), clopidogrel, ticlopidine or once daily aspirin of more than 81 mg.
10. Subject has any known diseases (not including controlled diabetes mellitus), infections or recent surgical procedures within 30 days of study initiation.
11. Subject knowingly has HIV or Hepatitis.
12. Subject has undergone administration of any investigational drug within 30 days of study initiation.
13. Subject has history of serious drug-related reactions, including hypersensitivity to tri-cyclic anti-depressants.
14. Subject has limited mental capacity or language skills such that simple instructions cannot be followed or information regarding adverse events cannot be provided.

Date of first enrolment
01/09/2004

Date of final enrolment
01/03/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Periodontology Unit
London
United Kingdom
WC1X 8LD

Sponsor information

Organisation
CombinatorX (USA)

Sponsor details
650 Albany Street
Boston
United States of America
02118

Sponsor type
Industry

Website
http://www.combinatorx.com/

ROR
https://ror.org/0496m6d18

Funder(s)

Funder type
Industry

Funder Name
CombinatorX (USA)

Alternative Name(s)
CombinatoRx

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration