

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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Single-center blinded placebo-controlled randomized study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

Study participating centre

Periodontology Unit

London

United Kingdom

WC1X 8LD

Sponsor information

Organisation

CombinatorX (USA)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration