

Investigation of the effect of treatment of maternal chronic periodontitis on delivery and low birth weight

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 15/12/2008	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
REC00165

Study information

Scientific Title

Study objectives

4,000 women will be examined at an early stage of their pregnancy and the 7.5% with the worst period periodontal condition will be randomly assigned to either intensive periodontal treatment or normal care. Data on pregnancy outcome will be collected for all subjects. The major objective is to establish whether the potential adverse effect of chronic periodontitis on pregnancy outcome can be prevented by treatment during pregnancy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic periodontitis during pregnancy

Interventions

1. Intensive periodontal treatment
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Proportion of mothers in sample having small babies

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/10/2001

Eligibility

Key inclusion criteria

4,000 pregnant women will receive a periodontal examination, from which the 300 most severe cases will be invited to participate in the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/1998

Date of final enrolment

01/10/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

GKT

London

United Kingdom

SE1 9RT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/09/2004		Yes	No