ISRCTN03350903 https://doi.org/10.1186/ISRCTN03350903

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 15/12/2008	**Condition category** Oral Health	

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

Primary study design
Interventional

Study design
Randomised controlled trial

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