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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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
Chronic periodontitis during pregnancy

Interventions
1. Intensive periodontal treatment
2. Standard care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Proportion of mothers in sample having small babies

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1998

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

Age group
Adult

Sex
Female

Target number of participants
300

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
England

United Kingdom

Study participating centre
GKT
London
United Kingdom
SE1 9RT

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive London (UK)

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

Study outputs

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