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Modification of the oral microbiome of periodontal pregnant women and babies after a preventive oral health program during pregnancy

Submission date
21/12/2024

Recruitment status
Recruiting

Registration date
27/12/2024

Overall study status
Ongoing

Last Edited
03/09/2026

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study, conducted at the University Dental Clinic of the University of Murcia, aims to evaluate the effects of an oral health prevention program on pregnant women with gum disease and its impact on their babies. The background and justification is that periodontal disease, common in pregnant women, is linked to complications such as preeclampsia, premature birth, and low birth weight. Changes in the oral microbiome during pregnancy can increase the risk of gum disease, which may affect both the mother and the baby. This study seeks to address these changes with a preventive program to improve oral health, reduce bacterial transmission, and lower pregnancy-related risks.

Who can participate?
Pregnant women who are at least 16 weeks pregnant with diagnosed with gum disease

What does the study involve?
The study involves two groups: the control group, which receives basic oral health education, and the intervention group, which receives additional treatments like fluoride, chlorhexidine mouthwash, and professional cleanings. Participants will be monitored during pregnancy and after childbirth, with oral samples taken from both the mother and baby.

What are the possible benefits and risks of participating?
Benefits: Participants may experience improved oral health, reduced risks of complications like preeclampsia, and lower bacterial transmission to their babies.
Risks: The study involves minimal risks, mainly related to the collection of oral samples and the treatments, which are generally safe.

Where is the study run from?
The University of Murcia

When is the study starting and how long is it expected to run for?
The study began in April 2024 after receiving approval from ethics committees and is expected to last until the babies are 1 year old.

Who is funding the study?
The University of Murcia, Yolanda Martínez Beneyto who is a professor and researcher at the University of Murcia and Elena Sánchez-Guerrero Sánchez, who is a researcher at the University of Murcia too.

Who is the main contact?
1. Elena Sánchez-Guerrero Sánchez, elenasanchezgs2@gmail.com
2. Yolanda Martínez Beneyto, yolandam@um.es

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Modification of the oral microbiome of periodontal pregnant women and babies after the implementation of a preventive oral health program during the gestation period

Acronym
MOMPREP

Study objectives
The implementation of a comprehensive oral health prevention program during pregnancy in women with periodontal disease will significantly improve the oral health profile of the mothers, reduce the pathogenic bacterial load in the maternal oral microbiota, decrease the risks associated with pregnancy complications (such as diabetes, preeclampsia, and preterm birth), and promote the transmission of a healthier oral microbiota to newborns, resulting in a reduction in the incidence of caries and periodontal disease in both mothers and babies, while also improving knowledge and oral health practices in pregnant women.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 12/04/2024, Comisión de Ética de Investigación (CEI), in english would be "Research Ethics Commission" (Edificio ESIUM, 3ª planta Campus de Espinardo, Murcia, 30071, Spain; +34 868883614; comision.etica.investigacion@um.es), ref: M10/2024/037

2. Approved 21/03/2024, Comité de Bioseguridad en Experimentación (CBE), in english would be "Committee on Biosafety in Experimentation" (Edificio ESIUM, 3ª planta Campus de Espinardo, Murcia, 30071, Spain; +34 868883614; comision.etica.investigacion@um.es), ref: 567/2023

Primary study design
Interventional

Study design
Single-centre interventional single-blinded randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of complications arising from periodontal disease and improvement of oral health in pregnant periodontal patients, as well as in their babies.

Interventions
This is a randomized clinical trial to evaluate the impact of a preventive oral health program in 50 pregnant women with periodontal disease (intervention group) and 50 pregnant women with no intervention (control group). In Visit 1, a comprehensive review will be conducted, including medical history, oral health education, OHIP-14 questionnaire, and bacterial plaque samples for microbiological analysis. Both groups will receive oral hygiene techniques, but the intervention group will additionally be instructed to use chlorhexidine mouthwash for one week each month (morning and night), a special toothbrush with replacements every 2-3 months, special

toothpaste for gum health, and gum mouthwashes (without chlorhexidine) during the 3 weeks off from chlorhexidine use. The intervention group will also receive treatments such as fluoride varnish and, if needed, scaling and root planing.

Both groups will have two follow-up visits during pregnancy. In the intervention group, additional appointments will be scheduled for necessary treatments (cleanings and/or scaling and root planing). After delivery, both groups will be revisited along with their babies. Saliva and cheek swab samples will be collected from the mother and the baby. For the mother, subgingival microbiota samples will be taken using absorbent paper tips at the beginning of the study, approximately one month before delivery, and after delivery (at 3-4 months), alongside the baby's samples.

All samples will be stored in Eppendorf tubes with a stable medium called PBS (except for the baby’s saliva) and frozen at -19°C at the same University Dental Clinic where the interventions are performed, until further analysis.

Participants will be randomly assigned to the groups using an online software tool. Caries, periodontal disease indices, and oral health-related quality of life will be measured at each visit, aiming to assess improvements in maternal oral health and reduce complications associated with periodontal disease.

Intervention Type
Mixed

Primary outcome(s)
Pathogenic oral microbiota in pregnant patients and their babies measured in subgingival microbiota samples collected using absorbent paper points inserted into deep periodontal pockets, guided by the CPITN scale (values 3-4) at three time points: during the first appointment (in the 2nd trimester of pregnancy), at the second appointment (end of the 3rd trimester) for all patients, and postpartum (4-5 months later). Additionally, samples of the baby's saliva and a cheek swab will be collected at the postpartum visit using the same absorbent paper points.

Key secondary outcome(s)
1. Oral Health-Related Quality of Life measured using test OHIP-14 (Oral Health Impact Profile) at the first visit.
2. Dental Caries measured using the ICDAS Index (Assesses caries detection and severity visually) and CAOD Index (measures decayed, missing, and filled teeth) at the first visit.
3. Periodontal Health measured using the CPI Index (Community Periodontal Index) (Measures periodontal disease severity through probing depths), Silness and Loe bleeding index (based on the observation of bleeding from the gingival margin when gently probing the gums, and it helps to determine the level of gingival inflammation) and O'Leary Plaque Index (Assesses plaque accumulation visually) at the first visit.
4. Baby's Oral Health measured using the Caries Index in Babies: Assesses early dental caries in primary teeth at the visit postpartum.
5. Oral Hygiene Knowledge and Practices measured using Oral hygiene and dietary questionnaires on the first visit.
6. General Health and Sociodemographic Data measured using Medical history and sociodemographic questionnaire at the first visit and last visit postpartum.
7. Obstetric Complications Related to Oral Health measured using Medical history and obstetric follow-up at the first visit and last visit postpartum.

8. Postpartum Follow-Up and Baby's Oral Health measured using Postpartum oral health evaluation at visit postpartum.

Completion date
30/09/2027

Eligibility

Key inclusion criteria
1. Pregnancy status: At least 16 weeks of gestation.
2. Screening: Completed screening with all results within normal parameters.
3. Decision to continue the pregnancy: The patient has decided to continue the pregnancy.
4. Diagnosis of periodontal disease: Diagnosed with periodontal disease at stages (I, II, III, IV) and grades (A, B, C) according to Tonetti et al. (2018).
5. Pregnancy risk: Pregnancy is not classified as high risk.
6. Mental health: No significant mental disabilities that would prevent participation in the study or extreme communication difficulties.
7. Informed consent: Acceptance of the informed consent and voluntary participation in the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Medical complications
2. Use of medications
3. Obstetric complications
4. History of psychiatric illness
5. Regular smokers or drinkers

Date of first enrolment
21/04/2024

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Spain

Study participating centre
Clínica odontológica universitaria de la Universidad de Murcia
Avenida Marqués de los Vélez, 2ª planta del Hospital Morales Meseguer
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Sponsor information

Organisation
Universidad de Murcia

ROR
https://ror.org/03p3aeb86

Funder(s)

Funder type
University/education

Funder Name
Universidad de Murcia

Alternative Name(s)
University of Murcia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location

Spain

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			23/12/2024	No	Yes