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A clinical study to investigate gum infection in patients on kidney dialysis

Submission date
12/06/2019

Recruitment status
No longer recruiting

Registration date
17/06/2019

Overall study status
Completed

Last Edited
21/08/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There are many studies in the last few decades that established a connection of plaque-induced periodontitis with other systemic diseases. The connection between periodontitis and chronic kidney disease is also studied. Chronic kidney disease is a progressive illness characterized by nephron destruction. Primary causes for that destruction are diabetes, pyelonephritis, glomerulonephritis, nephrosclerosis, polycystic kidney disease and collagen vascular diseases. The loss of kidney function leads to an accumulation of harmful metabolic products that can affect various organs. Clinical progress that leads to kidney failure can be divided into three progressive stages: first decreased kidney reserve, then decreased kidney function and at the end kidney failure or uremia. The last stage is treated either by dialysis or kidney transplantation. There are two types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis is a procedure in which nitrogen and other toxic metabolic waste products are removed from the blood by the hemodialysis system. The change between the patient's blood plasma and dialysate is made through a semipermeable membrane that allow uremic toxins to flow from the blood plasma. In peritoneal dialysis, dialysis fluid (called dialysate) is infused into the peritoneal cavity through the patient's catheter. The fluid (approximately 1-2- litres) is held (dwells) within the abdomen for a prescribed period of time. Hemodialysis is usually conducted three times a week for 3-4 hours and peritoneal dialysis is conducted at home or another clean environment each day. Peritoneal dialysis is cheaper and according to some research, it has a higher survival rate in the first two to four years. There is evidence that the quality of life is also better with peritoneal dialysis. But the percentage of patients on hemodiyalysis is higher.
Aim of the study: to compare periodontal status between patients on hemodialysis and peritoneal dialysis, analyze main laboratory parameters in relation to periodontal indices and by means of questionnaire determine oral hygienic habits, smoking habits and alcohol consumption in relation to dialysis type and periodontal status and to establish the need for periodontal therapy.

Who can participate?
Patients aged 18 and over on dialysis (peritoneal or hemodialysis).

What does the study involve?
Patients that attend Clinic of Internal Medicine, University Hospital Center “Sestre milosrdnice”,

Zagreb, Croatia and are on dialysis therapy (peritoneal or hemodialysis) are examined. All involved patients sign informed consent. The examination consists of taking periodontal indices: approximal plaque index, periodontal probing depth, periodontal bleeding index, bleeding on probing, gingival recession, clinical attachment level and calculation of periodontally inflamed surface area. All indices are measured at six sites on each tooth using a periodontal probe (PCP 15; Hu-Friedy, Chicago, IL, USA).

What are the possible benefits and risks of participating?
Benefits for the patients are free periodontal examination and free periodontal treatment if needed. The potential benefit is also decreased systemic inflammatory response and decreased mortality. There are no known risks.
Where is the study run from? Clinic of Internal Medicine, University Hospital Center “Sestre milosrdnice”, Zagreb, Croatia.
When is the study starting and how long is it expected to run for? February 2015-January 2016

Who is funding the study?
Funded by the main researcher.

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
EP-7326/14-11

Study information

Scientific Title
Periodontal indices in patients on hemodialysis and peritoneal dialysis: cross-sectional study

Study objectives
Patients on peritoneal dialysis have better periodontal status than patients on hemodialysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 11/06/2014, Ethics committee University hospital center “Sestre milosrdnice” (Vinogradska cesta 29, HR-10000, Zagreb, Croatia; +385 13787111), ref: EP-7326/14-11

2. Approved 12/02/2015, Ethics committee School of Dental medicine, University of Zagreb (Gunduliceva 5, HR-10000 Zagreb, Croatia), ref: 05-PA-26-6/2015.

Study design
Observational cross-sectional single-centre study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Periodontal infection in patients with end-stage kidney disease

Interventions
Before the dialysis procedure patients are examined by the same calibrated examiner. Patients fill a questionnaire about oral hygiene habits, alcohol consumption, smoking habits, education and sign informed consent. Laboratory tests that are usually taken on the day of dialysis are made available to the researcher by the Hospital.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Periodontal inflamed surface area (PISA). It is calculated based on bleeding on probing (BOP), clinical attachment level (CAL) and recession (REC) that are performed at six sites on each tooth. PISA is calculated by the on-line calculator available at: www.parsprototo.info.

Key secondary outcome(s))
1. Plaque index (Approximal plaque index API; Lange 1986.): approximal spaces in all four quadrants are measured only vestibular or oral and mark as presence or absence of plaque (+ or -). It is calculated as a percentage by the formula: API= number of sites with plaque (+)/ number of tested sites x 100
2. Periodontal bleeding index (PBI; Saxer and Muhlemann 1975.): there are four stages of bleeding sulcus after probing. All teeth in all four quadrants are probed. In first and third quadrant probing is done only on oral side and in second and fourth quadrant probing is done only on the vestibular side. PBI can be noted as bleeding number (sum of all bleeding values) or as the number of bleeding sites divided by the number of tested sites. Bleeding is provoked with blunt periodontal probe and light pressure from the papilla base to the top of papilla first in distal and then in the mesial sulcus. After 20-30 seconds when one quadrant is probed bleeding intensity is evaluated in four grades. Grade 1: only one point of blood is seen. Grade 2: blood line or several bleeding spots on gingival margin. Grade 3: interdental triangle is bleeding. Grade 4: profuse bleeding immediately after probing of interdental space
3. Periodontal probing depth: on six sites at each tooth-the distance between gingival margin and bottom of the sulcus or periodontal pocket in millimetres
4. Bleeding on probing (BOP; Ainamo and Bay, 1975.): on six teeth surfaces same as periodontal probing depth, without graduation, bleeding after probing is marked as + or -. It is presented as a percentage
5. Gingival recession: defined as the distance from cement-enamel junction till free gingival margin on six sites at each tooth. It is measured in millimetres

6. Clinical attachment level (CAL): is calculated by summing up periodontal probing depth and the distance from the gingival margin to the cementoenamel junction
7. Type of dialysis (hemodialysis or peritoneal dialysis)
8. Confounding variables that are statistically controlled:
8.1 Demographic and vital indicators: age, sex, education, smoking habits, alcohol consumption, height, weight, body mass index, nutritional state
8.2 Nephrological indicators: kidney disease, pharmacotherapy, duration of dialysis, dialysis access, main cardiovascular event
8.3 Dental indicators: self-reported xerostomia, frequency of dental examinations per year, frequency of tooth brushing and flossing, using of interdental brushes, self-reported bleeding during brushing
8.4 Laboratory and biochemical indicators (usually measured in dialysis patients): complete blood count, Kt/V (number used to quantify dialysis treatment adequacy), CRP (C-reactive protein), albumin in serum, lipidogram test, calcium and phosphorus in serum, PTH (parathormone).

Completion date
15/01/2016

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Kidney failure
3. Treated with hemodialysis or peritoneal dialysis.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
89

Key exclusion criteria
1. I-IV level of renal failure
2. Renal transplant patients

Date of first enrolment
03/02/2014

Date of final enrolment
15/12/2015

Locations

Countries of recruitment
Croatia

Study participating centre
Clinic of Internal Medicine, University Hospital Center Sestre milosrdnice
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Sponsor information

Organisation
School of Dentistry University of Zagreb

ROR
https://ror.org/00mv6sv71

Funder(s)

Funder type
Other

Funder Name
investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/04/2020	21/08/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes