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Sialolithiasis Epidemiology and Pathogenesis

Submission date
18/07/2012

Recruitment status
No longer recruiting

Registration date
17/10/2012

Overall study status
Completed

Last Edited
17/10/2012

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
The formation of salivary gland stone (sialolithiasis) is the most common disease of the salivary glands. The incidence has not been fully evaluated, neither in Denmark nor internationally. The composition of salivary gland stone are well described, but their cause remains unknown. Sialolithiasis is often associated with sialadenitis (painful inflammation of the salivary glands). It has not, however, been studied if bacterial infection plays a significant role for development of these conditions. Examination of saliva and salivary gland stones can help clarify the role of certain bacteria for development and pathology of sialolithiasis.
With the recent introduction of endoscopic treatment of the salivary gland (sialoendoscopy), it is now possible to remove stones from the duct of the gland. This provides a unique opportunity to investigate the composition of the salivary duct stones.
The aim of the project is to study the incidence of sialolithiasis, identify risk factors, evaluate the sialoendoscopic treatment and study whether biofilm (an aggregate of microorganisms in which cells adhere to each other on a surface) and bacteria contributes to stone formation. Other aspect of this study is to demonstrate that preserving the salivary gland and the salivary gland function by sialondoscopy is beneficial for the patients.
The project may enhance knowledge on the incidence, treatment and causes of sialolithiasis. Such knowledge may be of importance for future treatment and prevention of sialolithiasis.

Who can participate?
The study aims to recruit about 100 patients > 18 years (men and women) scheduled for sialendoscopy or surgical removal of the submandibular gland due to salivary gland stones in Denmark. The study recruits about 100 healthy volunteers >18 years as a control group.

What does the study involve?
The project is composed of an epidemiologic and a clinical part.
The epidemiologic part is based on data from the Danish Health Service databases, in which we will calculate the incidence of sialolithiasis and the distribution on sex, age and geography. We will look for possible hereditary factors as well as for an association between sialolithiasis and the presence of inorganic compounds in drinking water.
For the clinical part: Over a period of two years patients who are scheduled for surgical treatment of salivary gland stones will be invited to participate in the study. A control group of healthy individuals is also enrolled. The study will evaluate sialendoscopy as a method, and the importance of preserving the salivary gland and the salivary gland function. Also patients

salivary gland functions before and after sialendoscopy will be assessed. In addition, we will examine the oral health including risk of carries and test for changes in saliva content of enzymes. Patients expressed experience, of the effect of the treatment and their quality of life will be obtained. A blood sample will be obtained to see if patients with sialolithiasis have a higher level of certain hormone. Finally, we will examine the removed salivary stone, saliva and salivary gland tissue.
The healthy control group will undergo only sialometry and we will examine the bacteria and the chemical composition of the healthy saliva (organic and inorganic).

What are the possible benefits and risks of participating?
There will be no direct benefit from participating but the patient will gain an objective measurement for the effect of the surgical treatment. The study will benefit future patients with salivary gland stones because of enhanced knowledge on the disease.
Possible risks in the intervention group: Sialometry is not associated with any risks or discomfort . The blood sample is associated with short-term pain and can leave a bruise. The salivary gland scintigraphy will expose the patients to a low radiation dose (6 mSv)
The control group will undergo only sialometry .

Where is the study run from?
The study has been set up by Hillerød Hospital and Rigshospitalet, Denmark in collaboration with the Dentist school, Panum institute Denmark.

When is the study starting and how long is it expected to run for?
The recruitment started in May 2012. The recruitment period will last approximately 2 years; however the study will extend beyond this as we intend to look at the participants health over approximately 10 years to evaluate the long term outcome of the surgical treatment

Who is funding the study?
Funding has been provide by Hillerød Hospital Research foundation, ENT department Hillerød Hospital, Olga Bryde Nielsen foundation

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Obstructive salivary gland diseases pathogenesis, oral implications and evaluation on endoscopic guided diagnostic and treatment in preserving the salivary gland and salivary gland function

Study objectives
1. Biofilm is a pathogenetic factor in the formation of salivary stones.
2. In selective collected saliva from healthy individuals there is no growth of bacteria.
3. In selective collected saliva from the salivary stone patients bacteria can grow or bacterial products can be found by polymerase chain reaction (PCR) that correspond to bacteria cultured from saliva stone.
4. The chemical composition of the saliva (organic and inorganic) and parathyroid hormone (PTH) is different in patient with salivary gland stones compared to a control group of healthy individuals.
5. In Denmark there is an association of the incidence of sialolithiasis and the calcium level in drinking water.
6. Sialendoscopy is an effective treatment of salivary gland stones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific ethical committee of Region Hovedstaden Denmark, 24 April 2011, ref: Number H-4-2011-022

Primary study design
Observational

Study design
Clinical part: Case control trial
Epidemiological part: Registrar based population study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Sialolithiasis

Interventions
The patients group will undergo sialendoscopy or if sialendoscopy is not an option: surgical removal of the submandibular gland, sialometry, blood samples, questionnaire and salivary gland scintigraphy.

The healthy control group will undergo sialometry.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Sialometry (flow and chemical composition of saliva) - The patients are examined approximately 2 weeks (pre-operative examination) before the operation and approximately 3 month after (post-operative examination). The pre- and postoperative flow and the chemical composition of the saliva will be compared. Futhermore the chemical composition of the saliva will be compared to the control group.
2. The bacterial growth in salivary gland stones, salivary gland tissue and saliva will be examined after the tissue have been fixated approximately 1 week after operation.

Key secondary outcome(s)
1. To evaluate the effects of the sialendoscopy by comparing pre and post-operative salivary gland scintigraphy, and comparing pre- and postoperative saliva flow.
2. Subjective benefit from endoscopic treatment will be assessed 3 month post-operative by different questionnaires including quality of life assessment
3. Salivary gland scintigraphy
4. Blood samples from the patient will be taken 2 weeks before operation and compared to known values of parathyroid hormone (PTH) and calcium (Ca).

Completion date
01/05/2014

Eligibility

Key inclusion criteria
Patients with salivary gland stones subscribed for primary sialendoscopy or if sialendoscopy is not an option extirpation of submandibular gland. For the patients to undergo sialendoscopy stone must be verified by ultrasound examination or typical symptomatology.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

1. Age <18 years
2. Pregnancy, lactation
3. Continuous antibiotic treatment
4. Known stenosis
5. Use of mouth washes
6. Immunosuppressive therapy
7. HIV patients
8. Sjoegren's disease
9. Previous sialendoscopy

Date of first enrolment
01/05/2012

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Denmark

Study participating centre
ENT Department
Hillerød
Denmark
3400

Sponsor information

Organisation
Hillerød Resarch Foundation (Denmark)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hillerød Hospital Research Foundation (Denmark)

Funder Name
ENT department Hillerød Hospital (Denmark)

Funder Name
Olga Bryde Nielsen Foundation (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration