Quality of life and health in a sample of the Swedish general population

Study protocol

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Organisation

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Protocol summary

In the SSORG network there are several studies of different surgical interventions for prostate cancer, abdominoperineal excision for rectal cancer and rectal cancer patients at large, where we include questionnaires to the patients once or at several different time points. This enables us to get in-depth information about symptoms, their severity and duration but also their impact on quality of life. In order to obtain reference data we aim to ask a representative sample of Swedish inhabitants about symptoms from the urinary and gastro intestinal tract as well as psychological symptoms and sexual health together with questions about their socioeconomic situation. The information obtained will be used as reference data; to compare the frequency, duration and seriousness of for example stress symptoms in patients undergoing treatment for colorectal cancer, prostate cancer or diverticulitis a comparable group of Swedish women and men. The areas of interest in the questionnaire have been chosen with reference to the target patient groups from ongoing and coming studies/trials within the SSORG network.

Background

Reference populations, or "controls", are often needed in order to determine if a symptom or the functional level in a group of patients is a sign of their specific situation and disease related or just "life related" and to be found also in a reference group. In studies of health related quality of life, the established generic instruments such as SF 36 or EQ5D have results from reference populations. However for specific instruments, validated and constructed for certain groups of patients, this is not always the case. Obviously not all questions in such instruments are applicable to a reference group, but large parts of such questionnaires (instruments) are applicable and therefore it is of interest to study a reference group.

As we use specific questionnaires based on in depth interviews with patients, and expert validation in teams of experts participating in the care of specific groups of patients and finally face-to-face validated with patients, we are in need of reference data on some of the symptoms and functions included in the questionnaires used in groups of patients. In our studies of patients operated for prostate or rectal cancer we need to refer findings to "the average population" for symptoms like urinary and fecal incontinence, stress symptoms, sexual function, physical function and many more using the same questions that are used in patient questionnaires.

Thus the aim of this study is to study self-reported symptoms such as urinary incontinence, fecal incontinence, sexual function, the ability to walk and sit without

problems, negative thoughts (stress symptom),
depression and socioeconomic factors in a large group of Swedish inhabitants, women and men, in appropriate age groups.

Methods

The sample will include age groups of interest in relation to the patients in our trials. A questionnaire including many of the questions constructed for earlier and ongoing trials (APER, LAPPRO, QoLiRECT) will be used. These questions are based on in depth interviews with patients. The questions used in this study were adopted to be suitable for a sample from the "normal" Swedish population, and have been face-to-face validated before being used on the sample population.

An initial contact by letter to each individual will include information about the study and about the next step, a contact by phone from the study secretariate within a few days. The phone call will give an opportunity for renewed information and also a possibility for the individual to ask questions and receive answers about the study. The call will end with a question: "May I send the questionnaire to you by post?" and if the individual answers "yes" a letter including the information about the study (repeat), the "informed consent form" to be signed and returned and also the questionnaire and a pre-paid return envelope. If the answer is "no", no further contact is taken with this individual. If the individual cannot be reached by phone, the information letter (renewed), the consent form and the questionnaire is sent together with a prepaid answering envelope. A "Thank you"/ reminder letter is sent after two weeks. If the questionnaire has not been returned a phone call is made two weeks after that. That is the end of contact. In groups of patients this approach of events usually results in compliance of about 90%.

The sample restricted only by age includes 3000 individuals from the following age groups: 30-39, 40-49, 50-59, 60-69, 70-79 and 80-89 years. The Inland Revenue (Skatteverket) is asked to match in each age group for gender, urban/rural habitation, married/divorced etc, Swedish citizen and income in comparison to the general Swedish population. Application to the Region Ethical Committee in Gothenburg will be made.

The questionnaire includes a total of xxx questions, including KASAM, AUDIT and EQ5D. The "specific" questions have all been used in one or more studies of different patient populations.

Hypotheses

In a reference population, symptoms such as fecal or urinary leakage, erectile dysfunction and stress symptoms such as negative intrusive thoughts are less common than in a group of patients with rectal or prostate cancer. Health related quality of life is higher in the reference population compared with populations of patients.

End-points

To describe health related quality of life and psychological and socioeconomic situation in a Swedish reference population in order to compare the results to those in groups of patients.

Inclusion criteria

A representative sample of the Swedish population in age groups from 30 to 89 years, to a total of 3000 persons. The sample will be retrieved by the Swedish Inland Revenue.

Exclusion criteria

- No informed consent received.
- Withdrawn informed consent.

Inclusion and registration

A list of all individuals in the sample with full identification is supplied by the Swedish Inland Revenue. This is used to contact the persons (see above). Each of the 3000 individuals is given a study specific ID number, which is used to mark the questionnaires. Registration of included individuals as included in the study takes place when a signed consent-form has been received by the study secretariat, in a special inclusion list. The database uses only the study ID number.

Statistics and power calculation

If the participation is 70% the number of participating individuals will be 350 per 10 year age group. With this group size a prevalence estimate of symptoms and severity can be made down to differences of about 10% with a statistical power of 80%. The estimate is built on a binomial distribution approximation with a prevalence of 50% and a significance of 5%.

Publication

Results will be published in international peer reviewed journals. Common ("Vancouver criteria") criteria of co-authorship apply.

Work plan

After ethical permission has been and the sample from the "Swedish Inland revenue" with restriction as described have been obtained, we aim for the send out of questionnaires to take place during the last part of 2013 and early in 2014. Analysis of answers will be during 2014.

Data retrieval and registration

Questionnaires will be filed as original documents at the study secretariat and carefully stored for an anticipated time of at least 10 years. Collected data is transferred to a database during the course of the study. After completion of the database, data may be used for analysis and publication as described. Physically, the database is kept in a stationary PC connected to the university IT system and with back-up in the Gothenburg University server system, in order to satisfy high security standards with automatic back up and firewalls against external violation. The database is managed by the research statistician at the study secretariat. Both the Principal Investigator and the Deputy Principal Investigator should confirm any retrieval of data from the database. The database does not include the personal identity of the participants, only the unique study ID number. The datamanager will not have access to the code list, connecting personal ID to study ID. The code list will be possible to access only by those working with the contacting system and send outs, and the same persons will apply the study ID number to each questionnaire.

Ethical consideration

The Ethical Committee in Gothenburg has approved the study, Dnr XXXX-2013.

Study registration

The study is registered at clinicaltrials.gov

Financing

The study is supported by grants from The Swedish Cancer Foundation (Eva Haglind), Swedish Research Council (Eva Haglind & Eva Angenete) and ALF grants at Sahlgrenska University Hospital (Eva Haglind).

Work plan

Inclusion is scheduled to start during the fall 2013.