Title of the project: Use of retrospective samples and clinical information from cystic echinococcosis patients.

In charge: Dr Adriano Casulli, Istituto Superiore di Sanita’ (ISS), Rome, Italy

National Coordinator: … Add your name …

Financing Body: European Commission, Seventh Framework Programme (FP7), Grant number 602051, to Dr Adriano Casulli, Istituto Superiore di Sanita’ (ISS) Rome, Italy. Title: Human cystic Echinococcosis ReseArch in CentraL and Eastern Societies (HERACLES)

National Centres involved: … Add you centre …

Was the project scientifically evaluated? YES

Project summary

Rationale. Human cystic echinococcosis (CE), one of the most widespread helminthic zoonoses, is a chronic disease caused by infection with the larval stage of the tapeworm Echinococcus granulosus. This disease is highly endemic in some southern (Spain and Italy), eastern (Bulgaria and Romania) European countries and associated (Turkey) countries, where it still represents a major health and economic problem. In endemic areas the annual incidence of CE ranges from 1 to 200 per 100,000 inhabitants and 2-3 million cases are globally estimated. Case series and small clinical trials show a mortality rate of 2-4% for CE, but this increases markedly with substandard treatment and care. The diagnosis of human CE is mainly based on imaging techniques and serological confirmation. Clinical decision making is difficult and the natural history of the cyst is still poorly known. CE is chronic, complex and still neglected. For these reasons the objectives of HERACLES related with the use of retrospective samples and clinical information from cystic echinococcosis patients are:

• Establish a representative collection of blood/serum/plasma and parasite samples (hosted in the BioBank HERACLES) and associated clinical data (hosted in the database CYSTRACK; http://cystrack.irmasa.csic.es) from retrospective sampled patients;
• Validate new molecular-based POC-LOC kits for immunological surveillance, diagnosis and follow-up;
• Identify factor/s associated with CE response to therapy or lack thereof through investigation of host-parasite interplay (parasite virulence vs human immunity).

Main objectives. To create the Retrospective collection of samples and clinical information of CE patients in HERACLES. This collection will be implemented in the context of the FP7 European Project “HERACLES” (Human cystic Echinococcosis ReseArch in CentraL and Eastern Societies).

Secondary objectives. To stimulate basic and clinical research on the basis of the retrospective collection.

Main outcomes. Availability of samples and detailed clinical data (cyst localization, size, developmental stage, treatments performed), will give valuable tools for the development and validation of new tools to be applied in the improvement of the clinical management of CE. This will be an opportunity to study retrospectively and systematically the usefulness of newly developed diagnostic and follow-up devices, and to identify virulence markers. Collected samples and data will also give the opportunity to other researchers in the field to validate and develop new strategies for the clinical management of CE patients.

Population. All ages in- and out-patients seen from any date until December 2013 in the centers involved in the study, with confirmed CE diagnosis (by imaging, serology, and, where available, microscopic exam of cystic liquid).

Observational study

Study design. Former patients will be elected on the basis of the above reported criteria from any date until December 2013.

A biobank is a facility that houses and handles a collection of biological samples and the data derived from those samples, to be worldwide used for diagnostic, therapeutic or biomedical research purposes that need to be addressed with a minimum number of well characterized and stored samples. Biobanking is a key area to promote complete and evidence-based studies in different clinical and research fields, facilitating the proper management of samples and associated data, and the access to those samples to researchers and clinicians. Biobanks have their own ethical committee deciding on the use and management of sample
hosted in the biobank. The HERACLES BIOBANK has been built complying with the European Directive 2006/123/CE. The CYSTRACK database has been built complying with the European (2000/C 364/01, and Directive 95/46/EC) regulation on the protection and use of personal data. Sensible data will be automatically anonymized with the assignment of a progressive number to each patient, which will facilitate data retrieval and avoid entry duplications. Each patient record will contain: 1) an epidemiologic part, including baseline demographic data, year of CE diagnosis and symptoms at the time of diagnosis, history of treatments, and 2) a clinical part (including CE stage, treatment, serology). Both parts will be filled out by the reporting physician.

**Schemes.** The implementation of Retrospective samples and clinical data in HERACLES does not imply any experimental intervention on patients.

**Clinical protocol.** Not Applicable

**Clinical responsibilities.** Not Applicable

**Civilian responsibilities.** Not Applicable

**Pediatric research.** Not applicable.

**Research products.** Scientific papers, relations to congresses

**Data property.** Anonymized cumulative data will be owned by persons in charge of participant centers.

**Declaration on conflict of interest.** It is excluded any conflict of interest of participant to the project.

**Research on legally or for their health status not competent persons.** Not Applicable

**Use of questionnaires.** No

**Care provider is informed/ not informed.** Not Applicable

**Motivation for the request of evaluation by the Ethics Committee.** The implementation of Retrospective samples and clinical data in HERACLES is only observational and does not involve clinical experimentation. The evaluation by the Ethics Committee is requested should any and not forecasted ethics problems may raise during its implementation.

**The study is:**

- Clinical trial on drugs or medical devices. NO
- Biomedical research involving preservation of biological material. YES
- The evaluation of a Coordinating Ethical Committee is present. YES