



Champalimaud
Foundation



International Watch & Wait database

Patient information

The IWWD is an international project initiated by the Champalimaud Foundation, Lisbon, Portugal, and EURECCA, acronym for European Registry of Cancer Care, based in Leiden, the Netherlands.

Principal Investigators:

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Purpose of the research

Currently, many different treatment strategies are being used to treat patients with rectal cancer. A selection of patients will undergo primary chemotherapy and/or radiotherapy. Often, this treatment is followed by surgery, usually with a temporary ostomy and in about one third of the patients a permanent colostomy. Besides the standard complications, there is also a considerable risk of temporary or permanent problems with sexual function, bladder function, and the function of the anal sphincter.

Some patients respond very well to the chemo- and/or radiotherapy and there is no sign of tumor after the treatment (complete response). We observe and wait as an alternative to surgery. Currently worldwide this “Watch and Wait” treatment has shown promising results. However, further

research of the long term effects of omitting surgery (Watch and Wait) after complete response is necessary. Participation in long term prospective observational studies will contribute to the understanding of this new treatment option.

Type of Research Intervention

Participating in this International Watch and Wait Database does not influence the treatment. Patient data will be anonymously stored in a secure database.

Participant Selection

Patients with a complete response after 12 weeks of chemotherapy and/or radiotherapy for rectal cancer will be able to participate in this study.

Voluntary Participation

Participation in this observational study is on a voluntary basis, patients should approve having information coded in the database for research questions to be answered.

Procedures

On each visit to the doctor for follow up/surveillance, information about the health status related to the rectal cancer will be entered in the database.

Risks

Since this study only concerns the registration of data, there are no risks involved.

Benefits

Benefits to participate are usually not foreseen at a short notice to the individual patient. The database will deliver a great value of information on a treatment that cannot be studied in a different way due to the nature of the treatment. Especially the long term effects will show the efficacy and safety of this treatment. If this study proves that a Watch and Wait treatment is a good and safe alternative option to surgery, this treatment can be offered to all future patients with rectal cancer.

Reimbursements

We will not be able to provide participants any reimbursement for their participation.

Confidentiality

We will not be sharing information about patients to anyone outside of the research team. The information that we collect from this research project will be kept private. Any patient information will be anonymized. The database used is certified, highly secured and is stored in a encrypted server called [ProMISe](#) that meets all the requirements for data-safety and privacy set by international law.



Sharing the Results

Sharing of the result will be done annually during a forum and by publications to appear in international scientific journals.

Right to Refuse or Withdraw

Participation is voluntary and includes the right to withdraw.