

Trial information sheet (contents):

- 1. Name of trial, identifying code and version**
- 2. Nature and purpose of trial**
 - 2.1. Medical background information of trial
 - 2.2. Trial funding and responsible parties
 - 2.3. Extent of trial and number of participants
- 3. Independent evaluation, verification, approval and permission of trial protocol**
- 4. Medicinal product investigated and reference product(s)**
 - 4.1. Information about the medicinal products investigated in the trial as well as other possible reference products (or placebos)
 - 4.2. Trial design and its effect on the use of the medicinal product investigated and the reference product, as well as other medicinal products
- 5. Participation in the trial**
 - 5.1. Participant's rights and voluntariness
 - 5.2. Informing about the trial and discussion about participation with family / child / minor
 - 5.3. Selection, pre-conditions and eligibility criteria of participants
 - 5.4. Predicted benefits and possible disadvantages and risks of the trial
 - 5.5. Alternative forms of treatment
- 6. About the trial**
 - 6.1. Trial schedule, duration of trial and possible follow-up
 - 6.2. Research methods, treatments and procedures, tests and experiments (including possible ionising radiation, risks for a developing foetus, genetic tests, tissue samples etc.)
 - 6.3. Participant's tasks (patient diary etc.) according to trial protocol
 - 6.4. Treatment after trial or after withdrawal
- 7. Privacy protection**
 - 7.1. Confidentiality of research data and participant's right to verify personal data
 - 7.2. Collection of data (all sources), storage, application, future application (e.g. the use of stored electric data for following new trials) and disposal, as well as right to verify and disclose information (extent of rights and all recipients of rights, other parties, persons)
 - 7.3. Reporting trial results (whether the participant can receive data pertaining to himself/herself)
- 8. Participant's insurance**
 - 8.1. The Finnish patient insurance during trial
 - 8.2. The Finnish pharmaceutical injuries insurance during trial
 - 8.3. Other possible additional insurance
- 9. Expenses caused by the trial, reimbursement of expenses and grounds for reimbursement**
- 10. Additional information and contact information of research personnel**