

Patient information
“ Anti-hCG vaccine as a contraceptive ”

The World Health Organization (WHO) has developed a vaccine against the pregnancy hormone hCG. In animal trials this vaccine has worked as an effective contraceptive. The purpose of the trial in question is to find out if that is the case also in humans.

If you are interested in participating in the trial you will go through a thorough clinical examination and laboratory tests, which have to be normal to allow you to participate in the trial. Furthermore you have to be between the age of 18 and 39, have regular menstruation cycles and have the need of a contraceptive.

The trial covers a period of 6-8 months. You will get three injections of the vaccine with an interval of 4-6 weeks. If the level of antibodies extends a certain value (1.5 nmol/l) we think that you are protected against pregnancy and as long as you have this level of antibodies you are not allowed to use other contraceptives. During this time you must come to the hospital twice, a month for control and laboratory tests. After the trial is finished we will follow you up with tests every three months for about two years, or until the antibodies in the blood have disappeared.

Previous trials of the vaccine indicates that you will not get any side-effects from the treatment. If you in spite of the treatment would get pregnant we recommend that you interrupt the pregnancy although available experiences have not shown that the vaccine could give rise to damage to the fetus.

We will cover for any possible extra expenses the controls at the hospital will bring to you.

Your participation in the trial is voluntary and you can interrupt it whenever you like.

A nurse is available day-time at tel. 08-729 21 28 if you get any problem or wish further information. This is also the nurse that you will meet at your visits to the hospital. You can also contact me at tel. 08/729 42 10 Monday-Thursday 07.15-07.45 a.m.

Marc Bygdeman
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Maternal hospital

This “Patient Information” was hanging out in Swedish as a preliminary information flyer at the Karolinska Institute of Stockholm in fall ‘93.

Please note the marked paragraphs:

“...you will not get any side-effects...”

“...you can interrupt the trial whenever you like...” (!)

Women who were interested in participating then got an information brochure with a consent form, edited by the World Health Organization WHO.

For further information on the trials in Sweden: see other materials in this documentation.