

Clinical studies

The Nanodetector has already been applied successfully in several clinical studies:

Prenatal study:

- Pregnant women: 36 subjects

Cancer studies:

- Breast cancer: more than 30 subjects
- Lung cancer: more than 35 subjects
- Prostate cancer: more than 15 subjects

The Proof-Of-Concept for the high sensitivity Nanodetector was already achieved for the detection of fetal trophoblast cells in pregnant women. In oncology this Proof-Of-Concept - the isolation of rare cells - could be confirmed. The detection rate of CTCs in cancer patients was more than 80 percent.

Conclusions

Currently the isolation of embryonic cells for the analytical exclusion or conformation of serious genetic disorders (chromosomal aberrations such as a trisomy, etc.) is only possible with the high risk amniocentesis.

In oncology the assessment of the malignancy of tumors is difficult, particularly in the initial stages of the disease.

The number of circulating tumor cells (CTC) is considered as a criteria of malignancy. The early detection of the CTCs allows to characterize them in terms of their molecular and carcinogenic properties and to use them as a basis of an effective personalized therapy.

The Nanodetector developed by GILUPI is able to replace amniocentesis.

In oncology it is a major step forward in the implementation of personalized therapy approaches and enabling doctors to closely follow therapy results.

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The Company

The young biotech company GILUPI GmbH, founded in 2006, is developing new diagnostic products on the basis of its own patented inventions in nanotechnology for the *in vivo* isolation and detection of rare cells out of the circulating blood. The company expects a highly worldwide demand for its innovative technology for early prenatal and oncologic diagnostics. For the development of this Nanodetector and its introduction into the market GILUPI GmbH has received financial support by different investors.

It is planned to launch the first certified product based on this technology by 2012.

The GILUPI products can be currently used for *in vitro* tests.

GILUPI GmbH is offering cooperations for clinical studies in the field of prenatal diagnostics.

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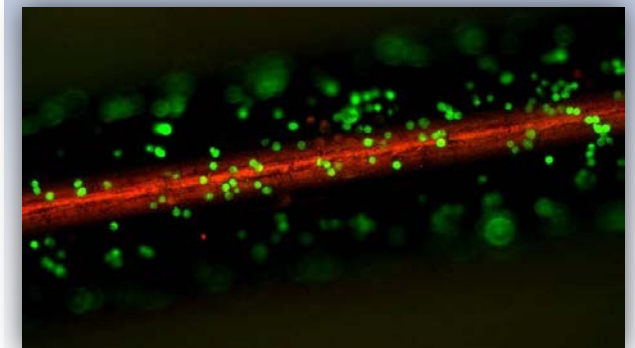
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Prenatal and Oncology

The Situation

The early detection of pathological changes is the decisive factor for their effective treatment and an improved quality of life of the patients. The methods currently used in hematological, immunological and cytological diagnostics are based on a limited sample volume. The limit of detection of rare cells in the sample is often not reached and this limitation reduces the chance of detecting pathological features.

In addition, the available diagnostic procedures are often burdened by a substantial physical and emotional stress for the patient (surgical procedures such as biopsy or amniocentesis, etc.)

Prenatal diagnostics

Currently used practices in prenatal diagnostics can be categorized in non-invasive and invasive techniques.

First of all non-invasive methods of screening (such as the Triple-Test) help estimating the risk of the presence of a fetal trisomy 21. If these tests indicate an increased risk, invasive procedures (Chorionic Villus biopsy, Amniocentesis) are recommended to the pregnant woman to confirm the supposed diagnosis. Amniocentesis can be performed from the 15th week of pregnancy. The risk of abortion is about 1 percent. The procedure developed by GILUPI can be used from up the 8th to the 10th week of pregnancy. In clinical studies health related risks for the fetus or the pregnant woman were not observed.

We offer our Nanodetector as a product, which is able to replace risky invasive methods.

In oncological diagnostics, the aim of the early detection of tumors is to install individual concepts for further action in order to improve the diagnostic and therapeutic concepts at the time of first evidence of a tumor disease. With our Nanodetector the diagnostic and therapeutic approaches including the real-time follow up of the therapy results can be optimized.

The chances of a successful therapy can be improved significantly and unnecessary treatments could be avoided.

The Approach

The GILUPI GmbH has developed a Nanodetector, which is an innovative approach to overcome present limitations of related diagnostic methods:

The usual way of isolating and examining cells from blood samples or other specimen will be replaced by a technique that uses the circulating blood of a patient for "fishing" certain cells.

- *in vivo* isolation of pathological cells (Trophoblasts, Circulating Tumor Cells, etc.) for
- molecular characterizations of these rare cells

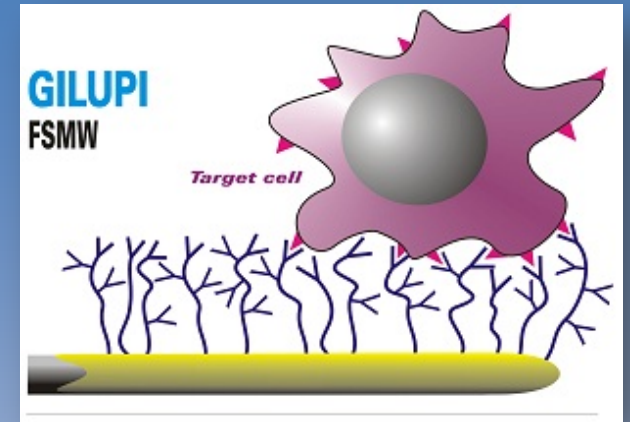
The Product

Fundamental features of the Nanodetector

(FSMW = Functionalized Structured Medical Wire):

- Medical stainless steel wire
- Coating of the wire with a three dimensional layer of a hydrogel or a polymer
- Functionalized surface using antibodies specific for the intended indication (prenatal, oncological)

The CE approval of this product will be achieved soon.



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Fig.1: Schematic Outline of the GILUPI Nanodetector

Usage

The Nanodetector will be positioned through a cannula in an arm vein for an intended contact time of 30 min.



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Fig. 2: GILUPI Nanodetector positioned in arm vein

Features

- Hardly incriminating screening for the patient
- Low risk application
- Very good biocompatibility
- Efficient isolation of rare cells
- No limited volume by sampling
- Increased chances of diagnostic sensitivity
- essential revised results compared to other standards of examination