A tissue bank for biomarker research on fresh frozen tumor samples

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a. Generate a tissuebank of fresh frozen tissue samples for biomarker research by establishing protocols and logistics for tissue collection, storage, annotation and retrieval. With additional goal the applicability in the standard clinical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON40050

Source
ToetsingOnline

Brief title
PamBrabant

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,PamGene BV

Intervention

Keyword: biomarker, proteomics, tissuebank

Outcome measures

Primary outcome

Generation of a tissuebank of fresh-frozen tumorsamples

Validation of the PamChip technology in terms of stability and logistics

Research on tumorspecific kinase profiles and their potential inhibitors

Research on predictive and prognostic biomarkers with the help of miRNA

expression profiles, phosphoproteomics and kinase profiles

Secondary outcome

not applicable

Study description

Background summary

Health research is focussing on the development of new drugs,improving their efficacy and reducing side effects. In this effort personalized medicine is an emerging field that promises significant changes by selecting the right patient for the right drug. Biomarkers - molecules or molecular activities linked to disease state - are the tools to facilitate this selection of patients and drugs. The access to patient derived biospecimens like tissues and blood is crucial to discover and validate these biomarkers. In addition such research will support the development of new drugs. Thus far, biomarker research has focussed on DNA, and tissue markers, which was based on using paraffin embedded and formalin fixed tissues. However, much information is lost in such samples, which would have been preserved if they were collected and stored freshly (*fresh frozen*). In recent years, the use of DNA and RNA arrays is increasing. Many new technologies like kinase activity profiling and phosphoproteomics,require these fresh frozen samples. Tissuebanking activities have been started in academic institutes while most samples can be collected in larger community hospitals. Generating a tissuebank in a community hospital is therefore very important. The availability of fresh frozen tumor samples will be increasingly important in the near future for the tailoring of the treatment

of many cancer patients. Not solely for the treatment of the primary tumor, but also for the treatment of possible metastases.
Biomarker research is lately also focussing on bloodsamples. Taking a bloodsample voor biomarker research will be increasingly important.
Also The Jeroen Bosch Hospital is and stays owner of the tissues from the tissuebank. PamGene BV can, for this study, only use the tissues offered by the Jeroen Bosch Hospital for research and only for the time of the research contract. Tissue and bloodsamples of patients, included in this study, could also be used for further biomarker research in collaboration with VU medical centre.

Study objective

a. Generate a tissuebank of fresh frozen tissue samples for biomarker research by establishing protocols and logistics for tissue collection, storage, annotation and retrieval. With additional goal the applicability in the standard clinical practice
b. Validation of the use of PamChip based kinase activity profiling on fresh frozen samples in term of robustness and logistics (qualitative analysis).
c. Generate a case in which samples from this tissuebank have been used in biomarker research using kinase activity profiling, starting by (1) exploring the heterogeneity of colorectal- and breast cancers, (2) possibilities for kinase activity based subtyping, and (3) new options for drug therapy in breast and colorectal cancer by testing ex-vivo and on-chip drug effects.
d. Further biomarker research, like phosphoproteomics and miRNA expression profiles on the tumor and bloodsamples in collaboration with VU medical centre

Study design

none interventional research at mentally competent subjects of 18 years or older who are operated for a maligancy

Study burden and risks

Except for the extraction of a bloodsample, no extra burden or risk are expected

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

malignant tumor starting with breast and colorectal cancer

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2011
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-11-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33661.028.10