BNT000-001 epidemiological study in CRC

Epidemiological study to determine the prevalence of ctDNA positivity in participants with Stage II (high risk) or Stage III CRC after surgery with curative (R0) intent and subsequent adjuvant chemotherapy with monitoring of ctDNA during clinical follow-up

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Study concept

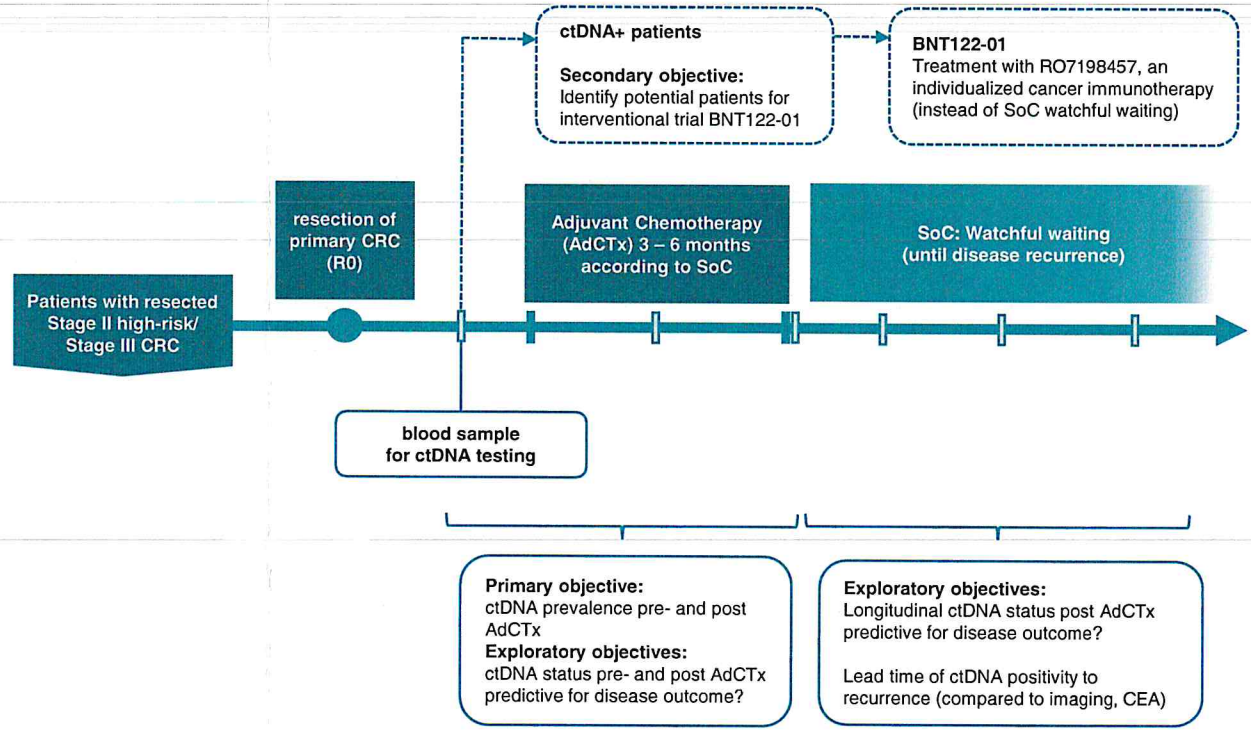
Stage II high-risk

As defined by at least one of the following criteria:

- T4
- Grade ≥ 3
- Clinical presentation with bowel obstruction or perforation
- Histological signs of vascular or lymphatic or perineural invasion
- Less than 12 lymph nodes examined

Stage III - all

- T1-3, N1 (low-risk stage III) and T4, N1-2
- T any, N2 (high-risk stage III)



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Study facts

- Patient screening window 4 – 8 weeks post tumor resection and before start of adjuvant chemotherapy
- Study visit for ctDNA blood sampling: within 7 days prior start of adjuvant chemotherapy
- Standard of care adjuvant chemotherapy does not need to be done at study site

- **Patients with positive ctDNA result post resection: High need for further treatment**

→ **Possiblity to transfer patients with a ctDNA+ patients to interventional study BNT122-01 testing the efficacy of an individualized immunotherapy after SoC adjuvant chemotherapy**

DRKS Studienregister: DRKS00025104

ClinicalTrials.gov: BNT000-001 (epidemiologische Studie): NCT04813627

BNT122-01 (interventionelle Studie): NCT04486378

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Pathology Information: Tissue sample requirements

Background

- Pathologists provide pivotal tissue samples for ctDNA analysis
- Tumor tissue samples provided to BioNTech and commissioned central laboratories are used to cut curls for DNA and RNA isolation and sequencing as well as slides for tumor content determination. After completed analysis the remaining tissue sample is returned to the clinical site.
- Successful analysis of mutations is strongly dependent on the quality and quantity of invasive tumor tissue used.

Sample requirements

- Please provide **two FFPE tumor tissue samples**, if possible, to have backup samples available, which avoids time critical additional requests.
- If no FFPE tumor tissue samples can be provides, **curls and slides** can be cut at site and shipped. Not preferred due to effect of transport on sample quality.
- If analysis of the main sample fails (e.g. due to inadequate fixation), it is beneficial to provide an **infiltrated regional lymph node or a preoperative biopsy as backup** or alternative sample.
- Please preselect a representative sample with high content of invasive tumor. **Minimal required invasve tumor area is 10%.**
- Please choose a sample with **low necrotic area, low fatty tissue area and low surrounding normal tissue area** if possible. Extensive adenoma components should be avoided as well.

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