Determination of the Claudin 6 Status Using the BioNTech Diagnostics CLAUDENTIFY® 6 IHC-Assay for the BNT142-01 study (Clinical Trial)

Published: 11-10-2024
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To use the CE-marked CLAUDENTIFY®6 IHC-Assay as a pre-screening test to determine Claudin 6 protein expression in patients with histological or cytological documentation of a solid tumor that is metastatic or unresectable provided as a pathology...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON57052

Source
ToetsingOnline

Brief title
CL6IHC-CPS-01 (linked to BNT142-01) ICON #4781/0029 - IVD study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, tumors

Research involving
Human

Sponsors and support

Primary sponsor: BioNTech SE
Source(s) of monetary or material Support: the Sponsor as in B.7

Intervention

Keyword: BNT142, CLAUDENTIFY® 6 IHC-Assay, Claudin 6 protein

Outcome measures

Primary outcome

The objective of this specific IVDR submission is a Clinical Performance Study for the CLND6 IHC Assay, to confirm aspects of the device performance which cannot be determined by the analytical performance study. This is outlined in the CPSP on Page 6 (of 35), in the table under *Objective of the Device Clinical Performance Study* which states the objective is to use the CE-marked CLAUDENTIFY®6 IHC-Assay as a pre-screening test to determine Claudin 6 protein expression in patients with histological or cytological documentation of a solid tumor that is metastatic or unresectable provided as a pathology report. The outcome of the study is to determine CLDN6 expression in patients with histological or cytological documentation of a solid tumor that is metastatic or unresectable.

Secondary outcome

Not applicable.

Study description

Background summary

The scope of the Clinical Performance Study (CPS) is to investigate the

clinical performance of the CLAUDENTIFY® 6 IHC Assay, to determine Claudin 6 protein expression levels in formalin fixed, paraffin embedded (FFPE) neoplastic tissue samples in advanced ovarian, lung, or testicular cancer. The CLAUDENTIFY®6 IHC assay uses an immunohistochemistry (IHC) procedure for the detection of Claudin 6 protein expression in freshly collected or archived FFPE neoplastic tissue. A valid test result will be used as one of the inclusion/exclusion criteria to determine patient eligibility for the BNT142-01 clinical trial.
Cancer is the second leading cause of death globally and in 2020 was estimated to be responsible for 10 million deaths.1 In general, once a solid tumor has metastasized, with a few exceptions such as germ cell and some carcinoid tumors, 5-year survival rarely exceeds 25%.

Study objective

To use the CE-marked CLAUDENTIFY®6 IHC-Assay as a pre-screening test to determine Claudin 6 protein expression in patients with histological or cytological documentation of a solid tumor that is metastatic or unresectable provided as a pathology report.
Results of the test will be used as one of the inclusion/exclusion criteria to determine patient eligibility for BioNTech*s clinical trial BNT142-01.

Study design

This is a device for performance study using the CLAUDENTIFY®6 IHC-Assay in patients with advanced/metastatic ovarian (including fallopian tube and peritoneal), non-squamous NSCLC, endometrial, or testicular cancer, for inclusion in BioNTech*s BNT142-01 clinical trial.

Specimen Collection (FFPE tumor tissue)
1. FFPE tumor tissue from the surgical resection collected from the clinical sites.
2. Specimens shipped to the clinical testing laboratory, at ambient temperature.

Specimen processing
1. Specimens are processed as per the CLAUDENTIFY®6 IHC-Assay Instructions for Use.
a. Refer to the Instructions for Use: CLAUDENTIFY®6 IHC-Assay, Ref 90060
b. Refer to SOP-030-230, *CLDN6 Diagnostic Immunohistochemistry according to CLAUDENTIFY 6 Histology Kit.*

Stained Specimen Scoring
1. For the assessment of Claudin 6 staining, the membrane staining intensity is evaluated and documented. Staining intensities are classified in scores from 0, 1+, 2+ and 3+.
2. Human normal tissue and tumor cells of cancer tissues should always show a

staining intensity <= 1+ when stained with the Negative Control Reagent (NCR). Unspecific staining (background) might arise especially on erythrocytes/lumen of vessels, plasma cells, immune cells, oedema, or mucoid structures. Intensity of such signals should be <= 2+. The positive control containing formalin-fixed, paraffin-embedded fetal rabbit kidney tissue should always show a staining intensity >= 2+ of cells near the renal capsule and of the Bowman capsule when stained with the anti-human Claudin 6 monoclonal antibody. Other structures might show varying staining intensities from 0 to 2+ or 3+.

Reported Data Results Used in BNT142-01.

Intervention

The CLAUDENTIFY®6 IHC assay uses an immunohistochemistry (IHC) procedure for the detection of Claudin 6 protein expression in freshly collected or archived FFPE neoplastic tissue.

Study burden and risks

Risk of Laboratory Test Procedure:
Tumor sample will be tested with the IVD test at the BioNTech SE central testing laboratory. The test itself cannot harm the subject, as the subject will never be in contact with it. If the amount and quality of the tissue is not sufficient, the doctor may request a new biopsy to be collected to take part in the research (MAIN study BNT142-01). Preferably the subject's stored tumor tissue is used for this test used in the IVD study; however, if a new biopsy is collected, that may be used in the IVD study.

Risk of a false positive test result:
There is a risk that the IVD test will give a so-called *false positive* test result. False positive means that the IVD test result does not correctly show the presence of the CLDN6 protein.

Contacts

Public
BioNTech SE

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The CLAUDENTIFY®6 IHC-Assay will be used in this clinical performance study to qualitatively determine a patient*s Claudin 6 protein expression to identify patients who may be suitable for randomization into the BNT142-01 interventional trial to enrich for patients with a higher probability of benefit from BNT142 and excluding patients not expressing the tumor target. Complete Inclusion/Exclusion criteria for eligible participants has been defined in the Clinical Trial Protocol for BNT142-01.

Exclusion criteria

The CLAUDENTIFY®6 IHC-Assay will be used in this clinical performance study to qualitatively determine a patient*s Claudin 6 protein expression to identify patients who may be suitable for randomization into the BNT142-01 interventional trial to enrich for patients with a higher probability of benefit from BNT142 and excluding patients not expressing the tumor target. Complete Inclusion/Exclusion criteria for eligible participants has been defined in the Clinical Trial Protocol for BNT142-01.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2025
Enrollment:	96
Type:	Anticipated

Medical products/devices used

Generic name:	CLAUDENTIFY®6 IHC-Assay
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-10-2024
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL85463.000.24