Öffentlicher Titel: MAGE-A3 als adjuvante Immunotherapie des NSCLC
Wissenschaftlicher Titel: GSK1572932A Antigen-spezifische adjuvante Immuntherapie bei Patienten mit nicht-kleinzelligem Lungenkrebs
Kurztitel: MAGE3 (Magrit)
Studienart: multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase: Phase III
Erkrankung: THORAX: Nicht kleinzelliges Lungenkarzinom: Adjuvant
Ziele:
- Disease-free survival
- Overall survival, lung cancer-specific survival, disease-free specific survival
- Safety
Einschlusskriterien:
- Male or female patient with completely resected, pathologically proven stage IB, II or IIIA NSCLC.
- Written informed consent for MAGE-A3 expression screening on tumor biopsy has been obtained from the patient prior to shipment of the sample for expression testing (before or just after surgical resection), and written informed consent for the complete study has been obtained prior to the performance of any other protocol-specific procedure.
- Patient is 18 years of age at the time of signature of the first informed consent form.
- The patient's tumor shows expression of MAGE-A3 gene.
- The surgical technique for resection of the patient's tumor is anatomical, involving at least a lobectomy or a sleeve lobectomy;
- The mediastinal lymph node sampling is done according to study protocol guidelines;
- The patient is free of metastasis, as confirmed by a negative baseline computer tomogram (CT scan) of the chest, upper abdomen and CT scan or MRI of the brain. Other examinations should be performed as clinically indicated. Note that if randomization is taking place within 8 weeks after surgery, brain CT scans or brain MRI performed up to 4 weeks before surgery do not have to be repeated.
- ECOG performance status of 0, 1 or 2 at the time of randomization.
- Adequate bone-marrow reserve, adequate renal function and adequate hepatic function as assessed by standard laboratory criteria, and defined as: Absolute neutrophil count ≥1.0 x 10^9/L, Platelet count ≥75 x 10^9/L, Serum creatinine ≤1.5 times the Upper Limit of Normal (ULN) 3.0 times the ULN if due to platinum adjuvant chemotherapy, Total bilirubin ≤1.5 times the ULN, Alanine transaminase (ALAT) ≤2.5 times the ULN.
- If the patient is female, she must be of non-childbearing potential, i.e. have a current tubal ligation, hysterectomy, ovariectomy or be post menopausal, or if she is of childbearing potential, she must practice adequate contraception for 30 days prior to administration of study treatment, have a negative pregnancy test and continue such precautions during all study treatment period and for 2 months after completion of the injection series.
- In the view of the investigator, the patient can and will comply with the requirements of the protocol.

Ausschlusskriterien:
- The primary tumor was removed by segmentectomy or wedge resection.
- The patient shows any evidence of residual tumor after surgery.
- The patient has received any anti-cancer specific treatment, including radiotherapy, immunotherapy, chemotherapy or neo-adjuvant chemotherapy, except: For the treatment of previous malignancies as allowed by the protocol (i.e., non-melanoma skin cancers or carcinoma in situ of the cervix or effectively treated malignancy that has been in remission for over 5 years), Administration of adjuvant platinum-based chemotherapy for the treatment of the current NSCLC is allowed between surgery and randomization.

- The patient has previous or concomitant malignancies at other sites, except effectively treated non-melanoma skin cancers or carcinoma in situ of the cervix or effectively treated malignancy that has been in remission for over 5 years and highly likely to have been cured.

- History of allergic disease or reactions likely to be exacerbated by any component of the study investigational product.

- The patient has an autoimmune disease such as, but not limited to, multiple sclerosis, lupus, and inflammatory bowel disease. Patients with vitiligo are not excluded.

- The patient requires concomitant treatment with systemic corticosteroids, or any other immunosuppressive agents. Note: The use of prednisone, or equivalent, <0.5 mg/kg/day (absolute maximum 40 mg/day), or inhaled corticosteroids for COPD or topical steroids is permitted.

- The patient has received a major organ allograft.

- The patient is known to be HIV-positive.

- The patient has an uncontrolled bleeding disorder.

- The patient has uncontrolled congestive heart failure or hypertension, unstable heart disease (coronary artery disease or myocardial infarction) or uncontrolled arrhythmia at the time of enrolment.

- The patient needs home oxygenation.

- The patient has psychiatric or addictive disorders that may compromise his/her ability to give informed consent, or to comply with the trial procedures.

- The patient has other concurrent severe medical problems, unrelated to the malignancy, that would significantly limit full compliance with the study or expose the patient to unacceptable risk.

- The patient has received any investigational or non-registered medicinal product other than the study medication within the 30 days preceding the first dose of study medication, or plans to receive such a drug during the study period.

- For female patients: the patient is pregnant or lactating.

Alter 18 Jahre und älter
Molekularer Marker Mage-A3
Status Geschlossen
Beginn der Rekrutierung 01.12.2008
Sponsoren GlaxoSmithKline (Hauptsponsor)
Förderer GlaxoSmithKline
Registrierung in anderen Studienregistern ClinicalTrials NCT00480025 (primäres Register)
EUDRACT 2007-001283-73
Therapie Antigenspezifische Immuntherapie (Impfung) im Vergleich zu Placebo nach erfolgreicher Operation und ggfs. adjuvanter Chemotherapie
Links Studien im Krankenhaus Nordwest