CIMAvax EGF treatment concomitant with first-line chemotherapy in NSCLC patients (stage IIIA non-surgical).

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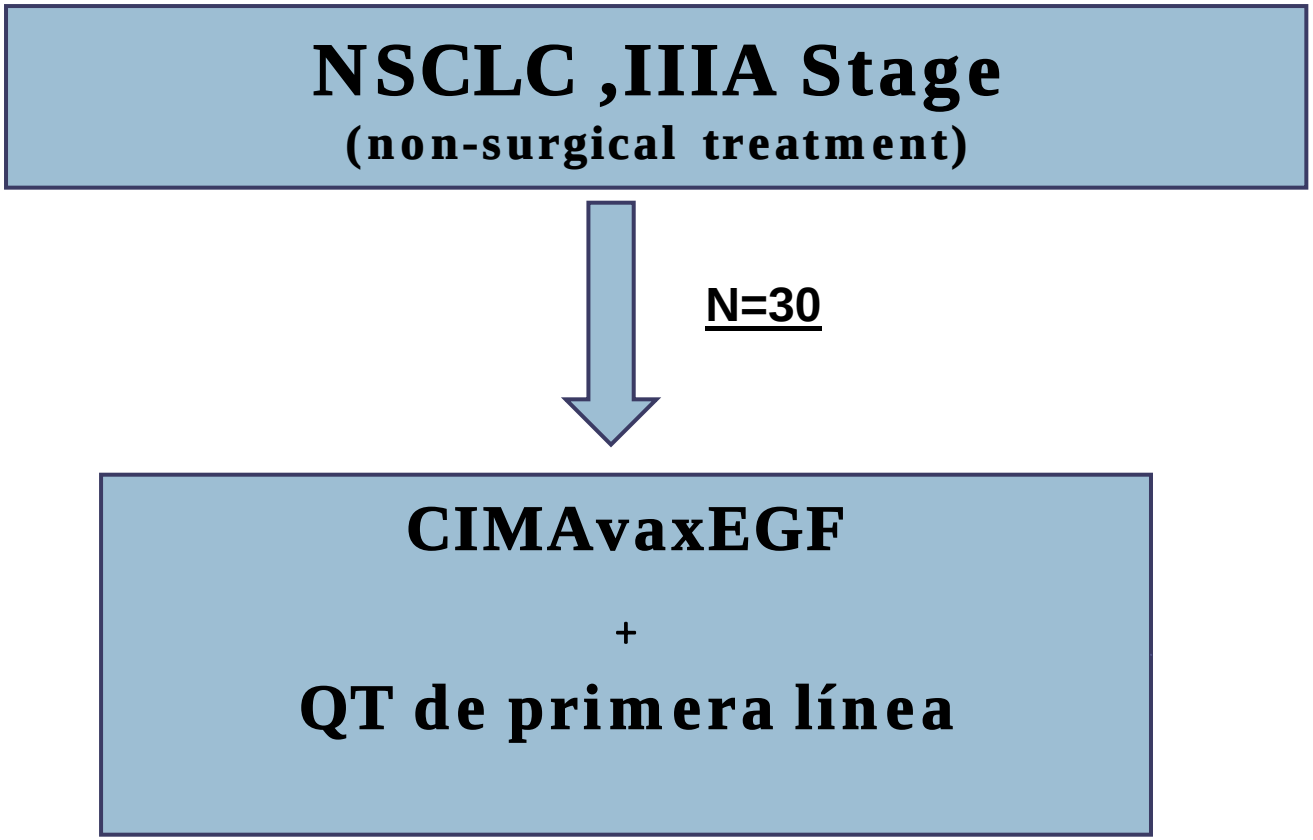
STUDY DESIGN



Exploratory study, single-center,single arm.

ENDPOINTS:

Primary:

Safety of CimaVax EGF concomitantly with first-line chemotherapy in patients with NSCLC stage IIIA (non-surgical treatment).

Secondary:
Overall survival time of patients with NSCLC stage IIIA (non-surgical treatment) treated with EGF CIMAVax concomitant with first-line chemotherapy and compared with historical controls.

Progression-free survivall time of patients with tumors of non-small cell lung stage IIIA non-surgical therapeutic vaccine treated with EGF CimaVax concomitant with first-line chemotherapy.

Humoral and cellular immune response of patients and correlate with clinical response.

INCLUSION CRITERIA:

-Patients with histological or cytological confirmation of NSCLC stage IIIA with non-surgical treatment option.

-Patients over 18 years.

-Ability to understand the study and voluntariness of the patient by signing the informed consent model.

-ECOG status ≤ 2 general

EXCLUSION CRITERIA:

-NSCLC patients with surgical treatment option.

-Patients who can not receive chemotherapy.

-Patients who have previously received the vaccine or therapeutic monoclonal antibody CIMAvaxEGF hR3.

-Patients who have received or are receiving other investigational product.

TREATMENT REGIMES:

Pre-treatment with cyclophosphamide: Day 1 (200 mg/m2)

CimaVax EGF:

The 1st immunization: Day 4
The 2nd immunization: Day 18
The 3rd immunization: DAY 32
The 4th immunization: DAY 46
The 5th immunization: DAY 76

Re-immunized: There will be monthly starting on the third month using the same dose to onset of unmanageable toxicity or worsening of general condition (up to 3 according to the ECOG scale .

CRITERIA FOR DISCONTINUATION:

- Serious or severe adverse events related to vaccination (according to the toxicity scale of the CTCAE v. 4).

- Changes in the patient's general condition that the investigator's discretion impede the administration of CIMAvax EGF.
  Patient's request or voluntary leaving.

- Intercurrent illness preventing further administration of treatment definitely.

- Pregnancy.

RESPONSE EVALUATION:

Safety:

EA type , Grade,Causality
Treatment duration
Current Results
Seriousness.

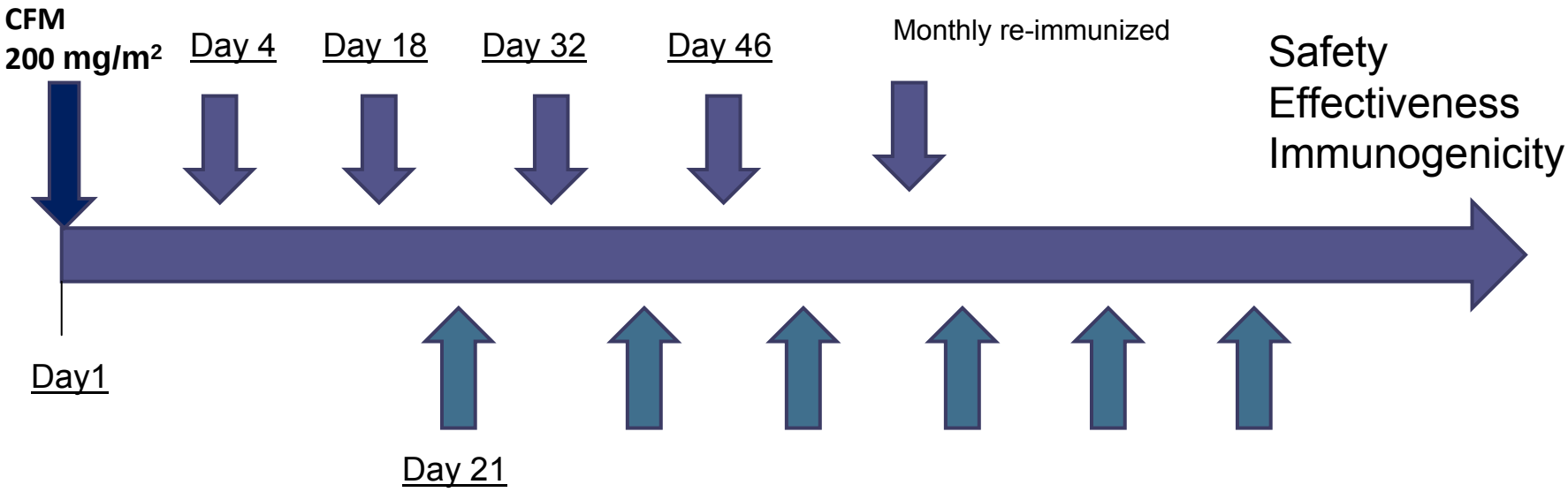
Effectiveness:

Overall survival, will be measured from the date of inclusion in the study until the date of death.
Progression-free time: measured from the start of treatment until the appearance of new lesions or progression of primary tumor using RECIST criteria.

Immunogenicity:

EGF concentration in serum.
Ac Titles against EGF in serum.

STUDY SCHEDULE



CHT (4 a 6 cycles)

CIMAvaxEGF

Thanks!!!