The Consort E-Flowchart Aug. 2005

Assessed for eligibility (n= 400)

Enrollment

Is it randomized?

Allocated to intervention HN3.8
(n=50)
Received allocated intervention
(n= 50)
Did not receive allocated intervention
(n=0)
Give reasons

Allocated to intervention HN3.8AD
(n=51)
Received allocated intervention
(n= 51)
Did not receive allocated intervention
(n=0)
Give reasons

Allocation

Lost to follow-up (n=0)
Give reasons
Discontinued intervention (n= 0)
Give reasons

Lost to follow-up (n=0)
Give reasons
Discontinued intervention (n= 0)
Give reasons

Follow-Up

Analyzed (n= 20)
Excluded from analysis (n=30)
Give reasons
Insufficient volume of serum available for this exploratory testing

Analysis

Excluded (n= 0)
Not meeting inclusion criteria
(n=0)
Refused to participate
(n=0)
Other reasons
(n=0)

Analysis

Excluded from analysis (n=31)
Give reasons
- Non compliance with blood sampling schedule (n=1)
- Insufficient volume of serum available for this exploratory testing (n=30)
The Consort E-Flowchart Aug. 2005

Assessed for eligibility (n= 400)

Excluded (n= 0)
- Not meeting inclusion criteria (n=0)
- Refused to participate (n=0)
- Other reasons (n=0)

Is it randomized?

Enrollment

Allocated to intervention HN7.5 (n=50)
- Received allocated intervention (n=50)
- Did not receive allocated intervention (n=0)
  Give reasons

Allocated to intervention HN7.5AD (n=50)
- Received allocated intervention (n=50)
- Did not receive allocated intervention (n=0)
  Give reasons

Lost to follow-up (n= 0)
  Give reasons

Discontinued intervention (n= 0)
  Give reasons

Lost to follow-up (n=0)
  Give reasons

Discontinued intervention (n= 0)
  Give reasons

Analysis

Analyzed (n= 0)
- Excluded from analysis (50)
  Give reasons
  - Non compliance with blood sampling schedule (n=1)
  - Subset not part of the exploratory Analysis reported here (n=49)
The Consort E-Flowchart Aug. 2005

Assessed for eligibility (n= 400)

Not meeting inclusion criteria (n=0)
Refused to participate (n=0)
Other reasons (n=0)

Is it randomized?

Allocated to intervention HN15 (n=50)
Received allocated intervention (n= 50)
Did not receive allocated intervention (n=0)
Give reasons

Allocated to intervention HN15AD (n= 50)
Received allocated intervention (n=50)
Did not receive allocated intervention (n=0)
Give reasons

Lost to follow-up (n= 0)
Give reasons
Discontinued intervention (n= 0)
Give reasons

Lost to follow-up (n=0)
Give reasons
Discontinued intervention (n= 0)
Give reasons

Analyzed (n= 0)
Excluded from analysis (n=50)
Give reasons
- Non compliance with blood sampling scheduel (n=1)
- Subset not part of the exploratory Analysis reported here (n=49)

Analyzed (n= 0)
Excluded from analysis (n=50)
Give reasons
- Non compliance with blood sampling scheduel (n=1)
- Subset not part of the exploratory Analysis reported here (n=49)
The Consort E-Flowchart Aug. 2005

Assessed for eligibility (n=400)

Enrollment

Is it randomized?

Excluded (n=0)
Not meeting inclusion criteria (n=0)
Refused to participate (n=0)
Other reasons (n=0)

Allocated to intervention HN30 (n=50)
Received allocated intervention (n=50)
Did not receive allocated intervention (n=0)
Give reasons

Allocated to intervention HN30AD (n=49)
Received allocated intervention (n=49)
Did not receive allocated intervention (n=0)
Give reasons

Lost to follow-up (n=0)
Give reasons
Discontinued intervention (n=0)
Give reasons

Lost to follow-up (n=0)
Give reasons
Discontinued intervention (n=0)
Give reasons

Analyzed (n=0)
Excluded from analysis (n=50)
Give reasons
- Non compliance with blood sampling scheduel (n=1)
- Subset not part of the exploratory Analysis reported here (n=49)

Analyzed (n=0)
Excluded from analysis (n=49)
Give reasons
- Administration of vaccine forbidden in the protocol/protocol violation (n=1)
- Subset not part of the exploratory Analysis reported here (n=48)