

# Assessment of the safety and distribution of NVB302 in healthy volunteers

<b>Submission date</b> 03/08/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 16/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/04/2016	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Salvatore Febbraro

### Contact details

Simbec Research Limited  
Merthyr Tydfil  
United Kingdom  
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## Additional identifiers

### EudraCT/CTIS number

2011-002703-14

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

NVB302/001

## Study information

**Scientific Title**

A phase I, double-blind, randomised, placebo-controlled, dose escalating study to assess the safety, tolerability, and pharmacokinetics of single and multiple doses of NVB302 administered orally to healthy volunteers

**Study objectives**

To evaluate the safety and tolerability of single and multiple oral ascending doses of NVB302 in healthy male and female subjects

Please note that as of 23/10/2012, the following changes were made to this record:

1. The anticipated start date was updated from 24/08/2011 to 26/10/2011
2. The anticipated end date was updated from 21/12/2011 to 16/03/2012

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South East Wales Research Ethics Committee, 25/07/ 2011, ref: 11/WA/0205

**Study design**

Single and multiple dose, double-blind, randomised, placebo-controlled, single centre dose escalating Phase I study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Screening

**Participant information sheet**

Not provided at time of registration

**Health condition(s) or problem(s) studied**

Clostridium difficile infection

**Interventions**

Part A (Single dose): Up to five cohorts of eight subjects will be randomized to receive one of five single oral doses of NVB302 with a starting dose of 100mg or a single oral dose of Placebo. The dose of NVB302 will be administered in an ascending dose fashion from Cohort 1 to 5. Within each cohort, 6 subjects will receive NVB302 and 2 subjects will receive placebo. Subjects will be followed up for 10 days

Part B (Multiple dose): Up to four cohorts of eight subjects will be randomized to receive either 10 days of once daily oral doses of NVB302 (6 subjects) or 10 days of once daily oral doses of placebo (2 subjects). The dose range to be studied will be selected following review of the results from completed cohorts of Part A. Subjects will be followed up for a further 14 days

**Intervention Type**

Drug

**Phase**

Phase I

**Drug/device/biological/vaccine name(s)**

NVB302

**Primary outcome measure**

Safety: Measured by adverse events, vital signs, ECG and routine laboratory assessments.

**Secondary outcome measures**

Pharmacokinetic parameters:

1. Plasma: C<sub>max</sub>, T<sub>max</sub>, t<sub>1/2</sub>, AUC<sub>0-t</sub> and AUC<sub>0</sub>
2. Urine: A<sub>eu</sub> (Amount of drug excreted)
3. Faeces: A<sub>ef</sub> (Amount of drug excreted)

**Overall study start date**

26/10/2011

**Completion date**

16/03/2012

**Eligibility****Key inclusion criteria**

1. Healthy male and female subjects, between 18 and 64 years of age (inclusive)
2. Female subjects must be postmenopausal or surgically sterilised
3. Female subject of non-child bearing potential with negative pregnancy test at screening
4. Male subjects must be willing to use an effective method of contraception from day 1 until 3 months afterwards
5. Subject has a healthy gastro-intestinal (GI) tract with no clinically significant history of GI disease (including any disorder likely to influence drug absorption) or bowel surgery

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

64 Years

**Sex**

Both

**Target number of participants**

Maximum of 72 subjects

**Key exclusion criteria**

1. Any relevant abnormality in medical history or on examination, including history of dementia, or other psychiatric, neurological, immunological, respiratory or cardiovascular disorder
2. Presence of Clostridium difficile toxin in faecal sample
3. Participation in a clinical study of an unlicensed drug in the previous 16 weeks, or a marketed drug study within the previous 12 weeks
4. Known allergies, including allergy to drugs with a similar chemical structure or class to NVB302 (Type B lantibiotics) or its constituents

**Date of first enrolment**

26/10/2011

**Date of final enrolment**

16/03/2012

**Locations****Countries of recruitment**

United Kingdom

Wales

**Study participating centre**

**Simbec Research Limited**

Merthyr Tydfil

United Kingdom

CF48 4DR

**Sponsor information****Organisation**

Novacta Biosystems Limited (UK)

**Sponsor details**

c/o Mrs Anne Hancock

BioPark Hertfordshire

Broadwater Park  
Welwyn Garden City  
United Kingdom  
AL7 3AX

**Sponsor type**  
Industry

**Website**  
<http://www.novactabio.com/>

**ROR**  
<https://ror.org/03hyrhe39>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Novacta Biosystems Limited (UK)

## Results and Publications

**Publication and dissemination plan**  
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No