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Assessment of the safety and distribution of NVB302 in healthy volunteers

Submission date	Recruitment status	[X] Prospectively registered
03/08/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2016	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-002703-14

Protocol serial number
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

Study type(s)
Screening

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

Key secondary outcome(s))
Pharmacokinetic parameters:
1. Plasma: Cmax, Tmax, t½, AUC0-t and AUC0
2. Urine: Aeu (Amount of drug excreted)
3. Faeces: Aef (Amount of drug excreted)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
64 years

Sex
All

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)

ROR
https://ror.org/03hyrhe39

Funder(s)

Funder type
Industry

Funder Name
Novacta Biosystems Limited (UK)

Results and Publications

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes