A Phase I trial to investigate the effect of nintedanib on the pharmacokinetics of a combination of ethinylestradiol and levonorgestrel in female patients with Systemic Sclerosis associated Interstitial Lung Disease (SSc-ILD) (1199-0340)

First published: 12/03/2021

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS40026

Study ID

40027

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] France
- [ ] Germany
- [ ] Netherlands
- [ ] Portugal
- [ ] Spain

Study description

A study to test whether nintedanib influences the components of birth-control pills in women with Systemic Sclerosis associated Interstitial Lung Disease (SSc-ILD)

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 10 centres are involved in the study

Contact details

Study institution contact

Boehringer Ingelheim clintriage.rdg@boehringer-ingelheim.com

Study contact

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Primary lead investigator

Mandy Avis

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/11/2017

Study start date

Actual: 08/11/2018

Data analysis start date

Actual: 15/11/2019

Date of final study report

Actual: 02/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Clinical trial

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Drug-drug interaction, pharmacokinetic trial

Data collection methods:

Primary data collection

Main study objective:

To investigate the effect of multiple oral doses of nintedanib on the single dose kinetics of a combination of ethinylestradiol and levonorgestrel (Microgynon®)

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Human pharmacology (Phase I)

Clinical trial randomisation

Non-randomised clinical trial

Study drug and medical condition

Medicinal product name

OFEV

Medicinal product name, other

Microgynon

Medical condition to be studied

Systemic sclerosis pulmonary

Population studied

Short description of the study population

Female patients aged 18 years or older with SSc-ILD fulfilling the 2013 ACR/EULAR classification criteria for SSc; extent of fibrotic lung disease ≥10% on high resolution computed tomography (HRCT); forced vital capacity (FVC) ≥40% of predicted;carbon monooxide diffusion capacity of the lung (DLCO) 30 TO 89% predicted. Patients had to be permanently sterilised or postmenopausal or using a highly effective non-hormonal method of birth control in combination with a barrier method.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Systemic Sclerosis associated Interstitial Lung Disease (SSc-ILD) patients

Estimated number of subjects

Study design details

Outcomes

AUC0-tz and Cmax for ethinylestradiol and levonorgestrel, AUC0-infinity for ethinylestradiol and levonorgestrel

Data analysis plan

Relative exposure of ethinylestradiol and levonorgestrel will be estimated based on the ratios (test to reference treatment) of the geometric means (gMeans) of the primary and secondary endpoints. Additionally, their 2-sided 90% confidence intervals (CIs) will be provided. The statistical model will be an analysis of variance (ANOVA) on the logarithmic scale, including effects for 'subject' and 'treatment'. CIs will be calculated based on the residual error from ANOVA. Descriptive statistics will be calculated for all endpoints.

Documents

Study results

1199-0340_report synopis_redacted for disclosure.pdf (862.16 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Interventional clinical trial data collection by investigational sites in an electronic clinical database.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No