

# A Phase 1b, randomized, partially double-blind, placebo-controlled study to assess the pharmacokinetics, safety, and tolerability of multiple doses of orally administered JNJ-53718678 in infants hospitalized with RSV infection

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**Primary Objectives:** The primary objectives are to evaluate in infants who are hospitalized with RSV infection:- the pharmacokinetics of JNJ-53718678 after multiple oral doses;- the safety and tolerability of JNJ-53718678 when administered for 7 days....

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Viral infectious disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON42680

### Source

ToetsingOnline

### Brief title

JNJ-53718678 in infants hospitalized with RSV infection

### Condition

- Viral infectious disorders

**Synonym**

respiratory Syncytial Virus infection, respiratory tract infection

**Research involving**

Human

**Sponsors and support**

**Primary sponsor:** Janssen Sciences Ireland UC

**Source(s) of monetary or material Support:** Janssen Science

**Intervention**

**Keyword:** Hospitalized, infants, Infection, RSV

**Outcome measures****Primary outcome**

The primary endpoints are:

- the pharmacokinetic parameters of JNJ-53718678;
- the safety/tolerability data including, but not limited to, AEs, physical examinations, vital signs, ECGs, and clinical laboratory results.

**Secondary outcome**

The secondary endpoints are:

RSV viral load as measured by qRT-PCR in nasal swabs will be used to determine the following;

- AUC of RSV viral load over time;
- viral load over time, peak viral load, and time to peak viral load;
- proportion of subjects reaching undetectability of virus between first

administration of study

drug and Day 28.

RSV clinical course endpoints including:

- Length of hospital stay from admission to discharge;
- Need and duration of supplemental oxygen requirement (type and duration [h]);
- Need and duration of intensive care unit stay;
- Need and duration of non-invasive ventilator support (eg, continuous positive airway pressure

[CPAP]);

- Number of hours until saturation >92% on room air;
- Need and duration of endotracheal mechanical ventilation;
- Evolution of respiratory rate, SpO<sub>2</sub>, and body temperature;
- Evolution of RSV symptoms as assessed by the clinician COA;
- Amount of food intake, hydration, and feeding by IV.

Exploratory endpoints are:

- Evolution of RSV symptoms as assessed by the parent/caregiver COA;
- Relationship between various pharmacokinetic parameters and RSV clinical course and antiviral endpoints;
- Impact of viral genotype on antiviral response;
- Sequence analysis of the RSV F-gene before treatment (at baseline), during

treatment, and

post-treatment, as applicable;

- Presence of co-infections at screening and detected retrospectively.

## Study description

### Background summary

Respiratory syncytial virus (RSV) is considered the most important virus causing acute lower respiratory tract infection (LRTI) and is a major cause of hospital admissions and death in young children worldwide.<sup>14,16</sup> Infants that are born prematurely or close to the RSV season and/or suffering from bronchopulmonary dysplasia or congenital heart disease are at the highest risk of developing severe RSV-related acute LRTI. In addition, RSV infection results in substantial illness and morbidity in the elderly and adults with underlying chronic illnesses, underlying disorders of cellular immunity, or suppressed immune systems.

### Study objective

Primary Objectives:

The primary objectives are to evaluate in infants who are hospitalized with RSV infection:

- the pharmacokinetics of JNJ-53718678 after multiple oral doses;
- the safety and tolerability of JNJ-53718678 when administered for 7 days.

Secondary Objectives:

The secondary objectives are to evaluate in infants who are hospitalized with RSV infection:

- the impact of JNJ-53718678 when administered for 7 days on the clinical course of RSV infection, as assessed by the clinician;
- the antiviral activity of JNJ-53718678 when administered for 7 days.

Exploratory Objectives:

The exploratory objectives are to assess in infants who are hospitalized with

RSV infection:

- the relationship between the pharmacokinetics and the pharmacodynamics after repeated

oral dosing of JNJ-53718678 for 7 days;

- the evolution of viral resistance under JNJ-53718678 treatment;

- the impact of the viral genotype on the antiviral response;

- the impact of JNJ-53718678 when administered for 7 days on the clinical course of RSV

during and following hospitalization as assessed by the subject\*s

parent(s)/caregiver(s) in the

electronic clinical outcome assessments (COAs) through end of follow-up.

## **Study design**

This is a Phase 1b, double-blind and placebo-controlled (except for the 1st cohort within each age group

which is open-label), randomized, multicenter, multiple ascending dose study in infants who are

hospitalized with RSV infection.

## **Intervention**

5 subject get JNJ-53718678 or placebo during 7 days.

## **Study burden and risks**

The subjects get JNJ-53718678 during 7 days. Furthermore nasal swabs and blood (max 3 times) will be taken from the subject. The subject need to be in the hospital for two days and there will be visits on day 7, 14 and 28.

No specific safety concerns were identified based on the currently available clinical data

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

1. Each subject\*s legally acceptable representative (ie, parent(s)/legal guardian/caregiver) must sign an ICF indicating that he or she understands the purpose of and procedures required for the study, are willing for their child to participate in the study, are willing for their child to remain in the hospital for the first 3 days of dosing (even if not clinically indicated), and are willing/able to adhere to the prohibitions and restrictions specified in the protocol (see Section 4.3) and study procedures.
2. Subject has presented at the hospital for suspected RSV infection within 72 hours prior to screening completion (ie, randomization).
3. Subject has been hospitalized for this suspected RSV infection.
4. Subject is a boy or a girl, who is >1 month to \*24 months of age on the day of randomization.
5. Subject has been diagnosed with RSV infection using a polymerase chain reaction (PCR)-based assay, preferably commercially available locally.  
Note: in case there is no commercially available PCR-based assay at the site, the Sponsor should be consulted for agreement on the assay to be used.
6. Subject was born after a normal term pregnancy (\*37 weeks and 0 days).
7. With the exception of the RSV-related illness, subject is otherwise in good health without any significant medical illness on the basis of a medical evaluation that reveals the absence of any clinically relevant abnormality and includes a physical examination, skin examination, medical history, vital signs, ECG, and the results of blood biochemistry, blood coagulation, and hematology tests performed at Screening. If there are abnormalities, the subject may be included only if the Investigator judges the abnormalities or deviations from normal to be not clinically significant. This determination must be recorded in the subject\*s source documents and initialed by the Investigator.

Note: Procedures that are standard of care and performed within 72 hours prior to screening completion (ie, randomization) may be used in determining study eligibility.

## Exclusion criteria

1. Subject is upon current admission initially hospitalized in the ICU and/or in need of invasive endotracheal mechanical ventilation.
2. Subject has a history of any illness or a concurrent illness that, in the opinion of the Investigator, might confound the results of the study or pose an additional risk in administering study drug to the subject or that could prevent, limit or confound the protocol-specified assessments. This may include, but is not limited to, bacteremia, gross abnormalities, organ dysfunction, or severe comorbidity.

Note: The use of intravenous fluids is not exclusionary as long as the Investigator believes the patient's gastrointestinal tract still functions properly (i.e., is able to absorb drugs or nutrition).

3. Subjects who had major surgery within the 28 days prior to randomization or planned major surgery through the course of the study.
4. Subject has major congenital anomalies (eg, AV shunt) or known cytogenetic disorders (eg, Down's syndrome).

Note: Open ductus arteriosus and open foramen ovale are not exclusionary as not considered major anomalies.

5. Subject has known or suspected immunodeficiency, such as known human immunodeficiency virus (HIV) infection.
6. Subject has known or suspected hepatitis B or C infection.
7. Subject has known allergies, hypersensitivity, or intolerance to JNJ-53718678 or its excipients.

## Study design

### Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL  
Recruitment status: Will not start  
Enrollment: 5  
Type: Anticipated

## Ethics review

Not approved  
Date: 18-12-2015  
Application type: First submission  
Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)  
  
Approved WMO  
Date: 05-01-2016  
Application type: First submission  
Review commission: CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
EudraCT	EUCTR2015-002003-28-NL
ClinicalTrials.gov	NCT02593851
CCMO	NL55415.000.15