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Terminated

Sponsor's decision

A Clinical Trial to Assess Safety and Pharmacokinetics of Fosnetupitant 235 mg and Metabolites in Healthy Volunteers

ClinicalTrials.gov ID NCT06840769

Sponsor Helsinn Healthcare SA

Information provided by Helsinn Healthcare SA (Responsible Party)

Last Update Posted 2025-05-04

Study Details Tab

Study Overview

Brief Summary

This clinical trial will include two parts, i.e., Part A and Part B.

The goal of the Part A is to define the shortest safe and tolerable duration of an intravenous injection of Fosnetupitant 235 mg solution among 4 durations tested in male and female adult healthy volunteers. In study part A, researchers will compare Fosnetupitant 235 mg solution to Akynzeo® solution.

The duration determined in Part A will be investigated in study Part B.

The Part B of the study was not performed.

Detailed Description

Feedback

HELSINN EXHIBIT 2027
Azurity Pharmaceuticals, Inc. v. Helsinn Healthcare S.A.
IPR2025-00949

The registered product Akynzeo® (235 mg fosnetupitant/0.25 mg palonosetron) solution for intravenous injection, used before chemotherapy, is to be diluted up to a final volume of 50 mL and administered during 30 min infusion. With the aim to facilitate and improve the use of this kind of products, the Sponsor Helsinn focused on the development of a ready to use solution, not requiring additional dilutions, and to be administered as a bolus injection. The product developed by Helsinn is a liquid formulation for infusion, containing exclusively fosnetupitant 235 mg free base.

Aim of the present open label, single dose, two parts (part A and part B) phase I study is to evaluate the safety and the pharmacokinetic profile of this new product, i.e., Fosnetupitant 235 mg ready to use solution for intravenous injection. In addition, the pharmacokinetic profile of fosnetupitant, netupitant (fosnetupitant is rapidly converted in netupitant after intravenous administration) and netupitant metabolites (M1, M2 and M3) will be investigated after a 30-min infusion of the registered Akynzeo® liquid formulation.

Part A of the study:

In cohort 1, 10 healthy volunteers will receive a dose of Fosnetupitant 235 mg solution as a one single 30-min intravenous infusion and additional 10 subjects will receive a single intravenous dose of Akynzeo® solution as a one single 30-min intravenous infusion, according to a parallel group design.

In each of 3 consecutive cohorts (cohorts 2, 3 and 4), 10 healthy volunteers will receive a single intravenous dose of Fosnetupitant 235 mg solution at a predefined infusion duration and will be sequentially treated as 3 subgroups of 3, 3, and 4 subjects, respectively.

A staggered approach with decreasing infusion time duration will be applied, from cohort 1 to cohort 4, to the administration of Fosnetupitant free base 235 mg solution, as follows:

Cohort 1: 30 min Cohort 2: 15 min Cohort 3: 5 min Cohort 4: 2 min

At the end of cohort 1 and of each subgroup of cohorts 2, 3 and 4, safety and tolerability results will be evaluated by the Investigator and the study Sponsor Medical Expert. Predefined stopping rules will be considered for deciding about continuing with the next cohort treatment and a shorter injection duration of Fosnetupitant 235 mg solution. Specifically, after cohort 1, if the injection duration of 30 min proves to be safe and well tolerated, 15 min injection duration will be tested in cohort 2. If the injection duration of 15 min proves to be safe and well-tolerated, 5 min injection duration will be tested in cohort 3. If the injection duration of 5 min proves to be safe and well tolerated, a 2 min injection will be tested in cohort 4.

The selected shortest (safe and tolerable) injection duration determined in Part A will be investigated in study Part B.

The study was prematurely terminated after the end of Part A and study Part B was not performed.

Official Title

A Phase I, Open Label, Single Dose, Two Parts Study in Male and Female Healthy Subjects to Assess the Safety and Pharmacokinetics of Fosnetupitant 235 mg Administered as IV Bolus and of Derived

Netupitant and Netupitant Metabolites

Conditions

Healthy Volunteers

Intervention / Treatment

- Drug: Fosnetupitant 235 mg solution
- Drug: Akynzeo solution

Other Study ID Numbers

Study Start (Actual)

2023-06-17

Primary Completion (Actual)

2023-10-18

Study Completion (Actual)

2023-10-23

Enrollment (Actual)

50

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library of Medicine

FDA Drug and Device Resources (https://clinicaltrials.gov/fda-links)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the Contacts and Locations section in How to Read a Study Record (https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations).

This study has 1 location

Switzerland

Canton Ticino Locations

Arzo, Canton Ticino, Switzerland, CH-6864
CROSS Research S.A.

Participation Criteria

Researchers look for people who fit a certain description, called eligibility criteria. Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read Learn About Studies (https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion criteria

1. Informed consent: signed written informed consent before inclusion in the study
2. Sex and Age: healthy men/women volunteers, 18-55 years old (inclusive)
3. Body Mass Index (BMI): 18.5-30 kg/m2 inclusive
4. Vital signs: systolic blood pressure 100-139 mmHg, diastolic blood pressure 50-89 mmHg, pulse rate 50-99 bpm, measured after 5 min at rest in the sitting position
5. Full comprehension: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study

6. Contraception and fertility (women only): women of childbearing potential defined as a non-menopausal woman who has not had a bilateral oophorectomy or medically documented ovarian failure and/or at risk for pregnancy must agree, signing the informed consent form, to use a highly effective method of contraception throughout the study and to continue for 14 days after the last dose of the study treatment. Highly effective contraceptive measures include:

    1. Hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit.
    2. A non-hormonal intrauterine device [IUD] for at least 2 months before the screening visit
    3. A sterile or vasectomized sexual partner
    4. True (long-term) heterosexual abstinence, defined as refraining from heterosexual intercourse when this is in line with the preferred and usual lifestyle of the subject, while periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods), lactational amenorrhea and withdrawal are not acceptable.

    Women of non-child-bearing potential or in post-menopausal status defined as such when there is either:

    1. 12 months of spontaneous amenorrhea or
    2. 6 months of spontaneous amenorrhea with serum FSH levels > 40 mIU/mL or
    3. 6 weeks documented postsurgical bilateral oophorectomy with or without hysterectomy will be admitted. For all women, pregnancy test result must be negative at screening and admission (Day -1).

7. Contraception (men only): men will either be sterile or agree to use one of the following approved methods of contraception from the first study drug administration until at least 14 days after the last administration, also in case their partner is currently pregnant:

1. A male condom with spermicide
2. A sterile sexual partner or a partner in post-menopausal status for at least one year
3. Use by the female sexual partner of an IUD, a female condom with spermicide, a contraceptive sponge with spermicide, a diaphragm with spermicide, a cervical cap with spermicide, or hormonal oral, implantable, transdermal, or injectable contraceptives for at least 2 months before the screening visit Men must accept to inform their partners of the participation in the clinical study. Furthermore, they will not donate sperm from the date of the informed consent form's signature, throughout the study, and for at least 14 days after the last dose of the study treatment. These requirements are based upon the availability and results of reproductive toxicity data.

Exclusion criteria

1. 12-leads Electrocardiogram (ECG) (supine position): clinically significant abnormalities at screening. With regards to QTc, the following will be considered as exclusion criterion: mean corrected QT (QTcF) > 450 ms. HR < 50 or > 99 bpm. PR < 100 or >220 ms. QRS > 120 ms. Relevantly abnormal T-wave patterns
2. Physical examination findings: clinically significant abnormal physical findings which could interfere with the objectives of the study
3. Laboratory analyses: clinically significant abnormal laboratory values at screening, indicative of physical illness or suggesting the subject's exclusion, in his/her best interest
4. Allergy: ascertained or presumptive hypersensitivity to the active principle and/or formulations' ingredients; history of anaphylaxis to drugs or allergic reactions in general, which the investigator considers may affect the outcome of the study
5. Diseases: significant history, in the opinion of the Investigator, of renal, hepatic, gastrointestinal, cardiovascular (in particular, heart failure, hypokalemia, family history of Long QT Syndrome, history of superficial thrombophlebitis or deep vein thrombosis), respiratory, skin, hematological, endocrine or neurological diseases that may interfere with the aim of the study
6. Medications: medications, including over the counter (OTC) medications and herbal remedies in the 2 weeks before the first visit of the study. Hormonal contraceptives for women are allowed
7. CYP3A4 inducers and inhibitors: use of any inducer or inhibitor of CYP3A4 enzymes (drugs, food, herbal remedies) in the 28 days or in the 7 days, respectively, before the planned first study drug administration and during the whole study
8. Investigative drug studies: participation in the evaluation of any investigational product for 3 months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study
9. Blood donation or significant blood loss: blood donations or significant blood loss in the 3 months before the first visit of this study
10. Drug, alcohol, caffeine, tobacco: history of drug, alcohol [>1 drink/day for women and >2 drinks/day for men, defined according to the USDA Dietary Guidelines 2020-2025 (11)], caffeine (>5 cups coffee/tea/day) or tobacco abuse (≥10 cigarettes/day)

11. Drug test: positive result at the urine drug screening test at screening or Day -1
12. Alcohol test: positive salivary alcohol test at Day -1
13. Diet: abnormal diets (<1600 or >3500 kcal/day) or substantial changes in eating habits in the 4 weeks before screening; vegetarians
14. Pregnancy (women only): positive or missing pregnancy test at screening or Day -1, pregnant or lactating women
15. Netupitant studies: enrolment in a previous study of netupitant or fosnetupitant (alone or in combination with palonosetron)

Ages Eligible for Study

18 Years to 55 Years (Adult)

Sexes Eligible for Study

All

Accepts Healthy Volunteers

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose : Health Services Research
Allocation : Non-Randomized
Interventional Model : Sequential Assignment
Interventional Model Description: Open label, single dose, two parts (part A and part B), safety and pharmacokinetic phase I study.
Masking : None (Open Label)

Arms and Interventions

Participant Group/Arm	Intervention/Treatment

Experimental: Study Part A - cohort 1
 	
Fosnetupitant free base 235 mg administered as single 30 min intravenous infusion or 235 mg fosnetupitant/0.25 mg palonosetron in 20 mL injection solution administered undiluted as a single 30 min intravenous infusion
	Drug: Fosnetupitant 235 mg solution
	
	• Fosnetupitant free base 235 mg (corresponding to 260 mg of the chloride hydrochloride salt) in 20 mL ready to use injectable solution for intravenous administration
	
	• Other Names:
	  ◦ Helsinn Fosnetupitant solution
	Drug: Akynzeo solution
	
	• 235 mg fosnetupitant (corresponding to 260 mg of the chloride hydrochloride salt) / 0.25 mg palonosetron in 20 mL injectable solution
	
	• Other Names:
	  ◦ IV Akynzeo®

Experimental: Study Part A - cohort 2 Fosnetupitant free base 235 mg administered as single 15 min intravenous infusion	Drug: Fosnetupitant 235 mg solution • Fosnetupitant free base 235 mg (corresponding to 260 mg of the chloride hydrochloride salt) in 20 mL ready to use injectable solution for intravenous administration • Other Names: ◦ Helsinn Fosnetupitant solution
Experimental: Study Part A - cohort 3 Fosnetupitant free base 235 mg administered as	Drug: Fosnetupitant 235 mg solution • Fosnetupitant free base 235 mg (corresponding to 260 mg of the chloride hydrochloride salt) in 20 mL ready to use

single 5 min intravenous infusion	injectable solution for intravenous administration • Other Names: ◦ Helsinn Fosnetupitant solution
Experimental: Study Part A - cohort 4 Fosnetupitant free base 235 mg administered as single 2 min intravenous infusion	Drug: Fosnetupitant 235 mg solution • Fosnetupitant free base 235 mg (corresponding to 260 mg of the chloride hydrochloride salt) in 20 mL ready to use injectable solution for intravenous administration • Other Names: ◦ Helsinn Fosnetupitant solution

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Study Part A: Number of Treatment-emergent Adverse Events	Number of treatment-emergent adverse events (TEAEs) collected up to 24 h post-dose.	From screening visit (day of informed consent signature) up to 24 h after the investigational medicin

		al product administration (a maximum of 21 days)
Study Part A: Number of Subjects With Treatment-emergent Adverse Events	Number of subjects with treatment-emergent adverse events (TEAEs) collected up to 24 h post-dose.	From screening visit (day of informed consent signature) up to 24 h after the investigational medicinal product administration (a maximum of 21 days)

Study Part A: Type of Treatment-emergent Adverse Events	Type of treatment-emergent adverse events (TEAEs) collected up to 24 h post-dose.	From screening visit (day of informed consent signature) up to 24 h after the investigational medicinal product administration (a maximum of 21 days)

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Study Part A: Systolic Blood Pressure	Systolic blood pressure in mmHg measured after 5 min at rest in sitting position	Screening visit/day -1 (enrolment day)/day 1 (treatm

		ent day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: Diastolic Blood Pressure	Diastolic blood pressure in mmHg measured after 5 min at rest in sitting position	Screening visit/day -1 (enrolment day)/day 1 (treatment day) at pre-administration, at the end of adminis

		tration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: Pulse Rate	Pulse rate in bpm measured after 5 min at rest in sitting position	Screening visit/day -1 (enrolment day)/day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of adminis

		tration/final visit (7 days after the treatment)
Study Part A: Weight	Body weight in kilograms	Screening visit (day of informed consent signature)/final visit (7 days after the treatment)
Study Part A: Full Physical Examination Through Apparatus/Systems Check	General appearance, Chest/respiratory, Gastrointestinal, Head, eyes, ears, nose and throat, Heart/cardiovascular, Lymph nodes, Metabolic/endocrine, Musculoskeletal/extremities, Neck (including thyroid), Neurological/psychiatric, Skin/dermatologic systems are checked. Any abnormalities are recorded.	Screening visit (day of informed consent signature)/final visit (7 days after the treatment)

Study Part A: Short Physical Examination Through Apparatus/Systems Check	General appearance, Chest/respiratory, Heart/cardiovascular, Lymph nodes, Neurologic/psychiatric, Skin/dermatologic systems are checked. Any abnormalities are recorded.	Day 2 (24 h after the end of investigational product administration)
Study Part A: ECGs - Heart Rate	Heart rate in beats/min recorded in supine position after 5 min at rest	Screening visit/day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)

Study Part A: ECGs - PR Interval	PR interval in ms recorded in supine position after 5 min at rest	Screening visit/ day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: ECGs - RR Interval	RR interval in ms recorded in supine position after 5 min at rest	Screening visit/ day 1 (treatment day) at pre-administration, at the end of adminis

		tration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: ECGs - QRS Duration	QRS duration in ms recorded in supine position after 5 min at rest	Screening visit/day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the

		treatment)
Study Part A: ECGs - QT Interval	QT interval in ms recorded in supine position after 5 min at rest	Screening visit/ day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: ECGs - QTcB Interval	QTcB interval in ms recorded in supine position after 5 min at rest	Screening visit/ day 1 (treatment day) at pre-administration, at the

		end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days after the treatment)
Study Part A: ECGs - QTcF Interval	QTcF interval in ms recorded in supine position after 5 min at rest	Screening visit/day 1 (treatment day) at pre-administration, at the end of administration and 1, 2, 4, 24 h after the end of administration/final visit (7 days

		after the treatment)
Study Part A: Clinical Laboratory Tests (Blood Chemistry, Haematology, Urinalysis)	Leukocytes and leukocyte differential count, erythrocytes, haemoglobin, haematocrit, MCV, MCH, MCHC, thrombocytes, electrolytes (sodium, potassium, calcium, chloride, inorganic phosphorus), enzymes (alkaline phosphatase, γ-GT, AST, ALT), substrates/metabolites (total bilirubin, creatinine, glucose, urea, uric acid, total cholesterol, triglycerides), total proteins, urine chemical analysis (pH, specific weight, appearance, color, nitrites, proteins, glucose, urobilinogen, bilirubin, ketones, hematic pigments, leukocytes), urine sediment (analysis performed only if positive: leukocytes, erythrocytes, flat cells, round cells, crystals, cylinders, mucus, bacteria, glomerular erythrocytes). Any abnormalities are recorded.	Screening visit (day of informed consent signature)/final visit (7 days after the treatment)
Study Part A: Cmax	Maximum plasma concentration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h

		after the administration
Study Part A: C0	Plasma concentration at the end of the administration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: Tmax	Time to achieve the maximum plasma concentration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3,

		4, 8, 12, 24 h after the administration
Study Part A: Clast	Last measurable plasma concentration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: Tlast	Time of last measurable plasma concentration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and

		at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: AUC0-t	Area under the concentration-time curve from time zero to time of last measurable plasma concentration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: AUC0-24	Area under the plasma concentration-time curve from time zero to 24 h after the administration measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3)	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30

		and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: Terminal Elimination Rate Constant	Terminal elimination rate constant, calculated, if feasible, by log-linear regression using at least 3 points, C0 and Cmax excluded and measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3). Calculation was not feasible for M1 and M3, therefore these analytes are not reported in the Outcome Measure Data Table.	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: t1/2	Apparent terminal half-life calculated, if feasible, by as ln2/terminal elimination rate constant and measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3). Calculation was not feasible for M1 and M3, therefore these	Day 1 (treatment day) at pre-administration, at 2, 5,

	analytes are not reported in the Outcome Measure Data Table.	10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: Systemic Clearance	Systemic clearance measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3). Calculation was not feasible for M1 and M3, therefore these analytes are not reported in the Outcome Measure Data Table.	Day 1 (treatment day) at pre-administration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the administration
Study Part A: Vz	Apparent volume of distribution in the post-distribution phase measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3). Calculation was not feasible for M1 and M3, therefore these	Day 1 (treatment day) at pre-adminis

	analytes are not reported in the Outcome Measure Data Table.	tration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the adminis tration
Study Part A: MRT	Mean residence time measured for plasma fosnetupitant, netupitant and its main metabolites (M1, M2 and M3). Calculation was not feasible for M1 and M3, therefore these analytes are not reported in the Outcome Measure Data Table.	Day 1 (treatm ent day) at pre-adminis tration, at 2, 5, 10, 15, 20, 30 and 45 min and at 1, 1.5, 2, 3, 4, 8, 12, 24 h after the adminis tration

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Helsinn Healthcare SA

Investigators

- Principal Investigator: Milko Radicioni, Cross Research S.A.

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2025-02-11

First Submitted that Met QC Criteria

2025-02-18

First Posted

2025-02-21

Results Reporting Dates

Results First Submitted

2025-03-25

Results First Submitted that Met QC Criteria

2025-04-16

Results First Posted

2025-05-04

Study Record Updates

Last Update Submitted that met QC Criteria

2025-04-16

Last Update Posted

2025-05-04

Last Verified

2025-04

More Information

Terms related to this study

Keywords Provided by Helsinn Healthcare SA

Helsinn
PNET-22-08
Fosnetupitant
Netupitant

Additional Relevant MeSH Terms

Pharmaceutical Solutions

HHS Vulnerability Disclosure

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

IPD Plan Description

No need to share IPD

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Study Documents **Provided by Helsinn Healthcare SA**

- Study Protocol (https://cdn.clinicaltrials.gov/large-docs/69/NCT06840769/Prot_000.pdf) [PDF, 1.3MB, 2023-05-24]
- Statistical Analysis Plan (https://cdn.clinicaltrials.gov/large-docs/69/NCT06840769/SAP_001.pdf) [PDF, 11.41MB, 2024-06-18]