

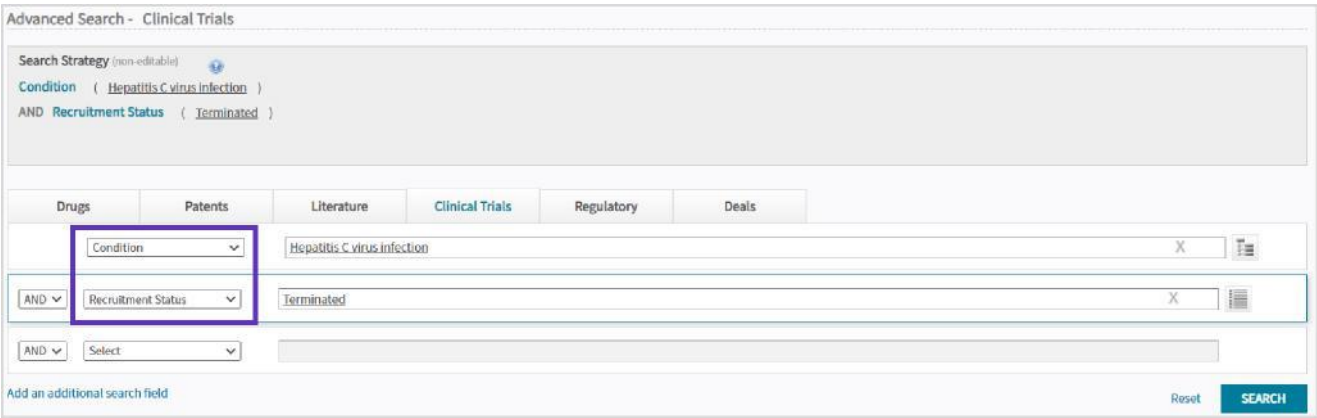
Cortellis Clinical Trials Intelligence

試験の中止理由を確認する

Cortellis Clinical Trials Intelligenceでは、試験の中止理由から収録試験を簡単に絞り込めます。被験者募集の問題なのか？安全性や有効性の観点から運営が厳しくなったのか？中止理由の索引が試験レコードに付与されていますので、効率的に試験中止に関する情報の検索と整理が可能です。

本資料ではC型肝炎を対象とする試験の中止理由を確認する手順を解説致します。

1. Advanced SearchにてClinical Trialsの検索フィールドにて、Condition(Hepatitis c virus infection)、Recruitment Status(Terminated)を選択し検索を実施します。



Advanced Search - Clinical Trials

Search Strategy (non-editable)

Condition (Hepatitis C virus infection)

AND Recruitment Status (Terminated)

Drugs Patents Literature Clinical Trials Regulatory Deals

Condition Hepatitis C virus infection

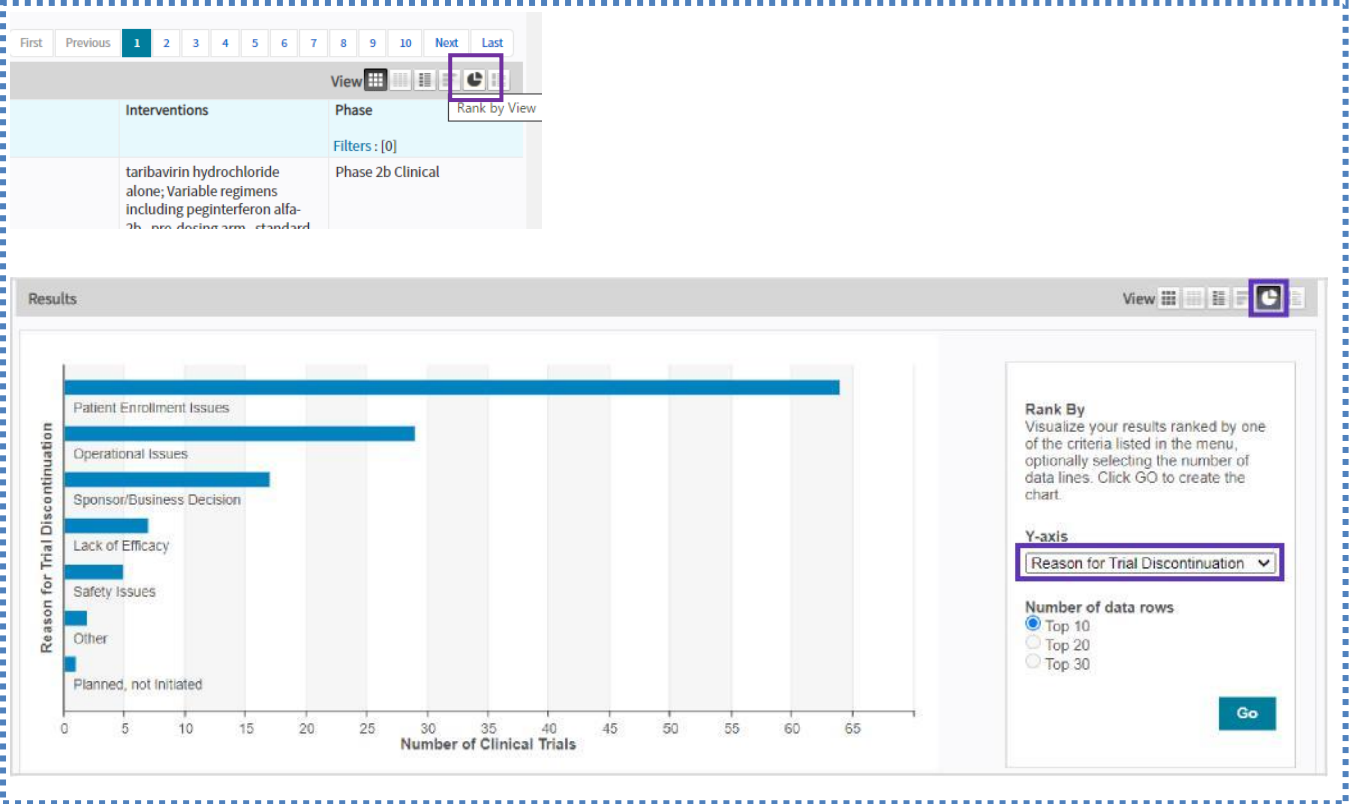
AND Recruitment Status Terminated

AND Select

Add an additional search field

Reset SEARCH

2. 検索結果一覧画面の表示をRank by Viewに切り替え、ランク形式の表示にてY軸の項目をReason for Trial Discontinuationに変更します。



3. チャートにて中止理由の項目のバーをクリックし（本事例ではLack of Efficacy）を選択すると、中止理由からしぼりこまれた試験結果一覧を表示します。デフォルトの表示形式であるTable Viewにて、対象試験におけるPatient Segment、Phase、エンドポイントやバイオマーカーが表示されます。

7 results found for ' Condition (Hepatitis C virus infection) AND Recruitment Status (Terminated) AND Reason for Trial Discontinuation (Lack of Efficacy) '

First Previous 1 Next Last

Results Per page: 25 Sort by: Last Change Date Most Recent Order Columns View

Title	Patient Segment	All Endpoints	Phase	Biomarkers	Adverse Events
Efficacy and Safety of Uptrifosbuvir (MK-3682) + Ruzasvir (MK-8408) in Treating Hepatitis C Virus Infection Genotypes 1 to 6	Filters : [0] Hepatitis C virus infection - Subjects Infected with HCV Genotype 1; Hepatitis C virus infection - Subjects Infected with HCV Genotype 2/3; Hepatitis C virus infection - Subjects Infected with HCV Genotype 4; Hepatitis C virus	Filters : [0] Hepatitis C virus infection - Assessment of Safety and Tolerability - Assessment of adverse events/serious adverse events; Hepatitis C virus infection - Assessment of Safety and Tolerability - Treatment-emergent adverse	Filters : [0] Phase 2 Clinical	Filters : [0] Hepatitis C virus RNA	Filters : [0]

4. レコードをクリックし、試験のレジメンやプロトコル、組み込み被験者の適格基準などから試験デザインを分析します。

Standard of Care (SOC) With or Without CTS-1027 in Hepatitis C (HCV) Null-Responders

Snapshot Highlight ☐ Search Terms & Synonyms < Previous Next >

Protocol & Results	PROTOCOL & RESULTS AIMS & SCOPE This study was a placebo-controlled, double-blind, multicenter study utilizing SOC (Pegasys + ribavirin) in combination with CTS-1027 in genotype 1 chronic HCV patients who were null-responders to previous SOC therapy(ies). Null-responders are defined as patients who failed to achieve an early virological response (EVR) at week 12 during previous SOC therapy. By February 2011, the first patient was treated [1169073]. PROTOCOL DESCRIPTION TEXT If, during previous SOC treatment, a patient had < 2 log decline in HCV-RNA at week 12 but > 2 log decline in HCV-RNA at any time from week 12 to 24, that patient was not a null-responder and was excluded from study participation. If, during previous SOC treatment, a week 12 HCV-RNA was not obtained, the post week 12 response must have been < 2 log decline (and still HCV-RNA positive) in order for the patient to be defined as a null-responder. Patients would be screened and have up to 4 weeks to qualify for study entry. During this screening period, clinical and laboratory tests would be performed. At week 0/day 1, patients would undergo centralized, stratified (based on ethnicity), randomization to one of four treatment arms: SOC (Pegasys + ribavirin) one of three doses of CTS-1027 or SOC + placebo. Study treatment would last 24, 48, or 60 weeks, based on each patient's response to study treatment. The principal investigators, other investigative site personnel, and patients would be blinded to the HCV-RNA results for the first 12 weeks of therapy. At week 12, the study treatment blind would be broken by the study's Interactive Web Randomization System (IWRS). However, the principal investigators, other investigative site personnel, patients, and Sponsor would remain blinded to treatment allocation until week 24 (see below). Patients on SOC + placebo who do not achieve at least a 2 log decline in their HCV-RNA at week 12 would be automatically rolled-over into the SOC + 15 mg two times a day (bid) arm. The treatment duration for these patients would be 60 weeks (ie, 12 weeks on SOC [Pegasys, 180 microg/week and ribavirin 1000 or 1200 mg/day] + placebo, followed by 48 weeks on SOC + CTS-1027 15 mg bid). Those patients on SOC + placebo who achieve >= 2 log decline at week 12 would continue on SOC therapy until week 48. Patients in the SOC + CTS-1027 arms would continue with the same treatment regimen for the initial 24 weeks regardless of HCV-RNA changes. At week 24, the study blind would be formally broken. Patients in the SOC + CTS-1027 arms who achieve >= 2 log HCV-RNA decline by week 24 would continue with the same treatment regimen they were assigned during the double-blind, phase for an additional 24 weeks. Patients in the SOC + CTS-1027 15 mg bid and the SOC + CTS-1027 30 mg bid arms who achieve < 2 log HCV-RNA decline by week 24 would dose-escalate to the next higher dose of CTS-1027 for an additional 24 weeks. Patients in the SOC + CTS-1027 60 mg bid arm who do not achieve at least a 2 log				
Subjects & Measurements	SUBJECTS & MEASUREMENTS ELIGIBILITY CRITERIA <table> <tr> <td>Inclusion Criteria Text</td> <td> - Male or female patients of minimum adult legal age (according to local laws for signing the informed consent document), able to provide written informed consent, and understand and comply with the requirements of the study - HCV genotype 1 infected null responders to prior therapy comprised of pegylated interferon and ribavirin (standard of care, SOC) defined as: - Failure to achieve an early virological response (< 2 log decline in HCV-RNA by week 12), or - If week 12 HCV-RNA was not obtained, post week 12 HCV-RNA response was < 2 log decline - Screening HCV-RNA viral load of > 5.0 log (ie, > 100,000 IU/ml) - Alpha-fetoprotein (AFP) <= 100 ng/ml - Hemoglobin >= 12 g/dl for women and >= 13 g/dl for men, hemoglobin A1c <= 7.5 %, platelet count >= 90 x 10(9)/l, and white blood cell count >= 1.5 x 10(9)/l - Thyroid Stimulating Hormone (TSH) within normal limits - In the opinion of the principal investigator, the patient met the 80/80/80% rule during the previous pegylated interferon and ribavirin therapy (ie, received at least 80% of the pegylated interferon and ribavirin doses, at least 80% of the dose size, for at least 80% of the treatment duration) - Willingness to utilize two reliable forms of contraception (for both males and females of childbearing potential) from screening to at least 6 months after the completion of the study </td> </tr> <tr> <td>Inclusion Criteria Index</td> <td> - Hepatitis C virus infection - Subjects with Chronic Hepatitis C Infection - Hepatitis C virus infection - Subjects with Positive Serological Markers for Hepatitis C - Subjects positive for HCV RNA - Hepatitis C virus infection - Subjects with Prior Hepatitis C Therapy - Hepatitis C virus infection - Subjects with Treatment Resistant Disease </td> </tr> </table>	Inclusion Criteria Text	- Male or female patients of minimum adult legal age (according to local laws for signing the informed consent document), able to provide written informed consent, and understand and comply with the requirements of the study - HCV genotype 1 infected null responders to prior therapy comprised of pegylated interferon and ribavirin (standard of care, SOC) defined as: - Failure to achieve an early virological response (< 2 log decline in HCV-RNA by week 12), or - If week 12 HCV-RNA was not obtained, post week 12 HCV-RNA response was < 2 log decline - Screening HCV-RNA viral load of > 5.0 log (ie, > 100,000 IU/ml) - Alpha-fetoprotein (AFP) <= 100 ng/ml - Hemoglobin >= 12 g/dl for women and >= 13 g/dl for men, hemoglobin A1c <= 7.5 %, platelet count >= 90 x 10(9)/l, and white blood cell count >= 1.5 x 10(9)/l - Thyroid Stimulating Hormone (TSH) within normal limits - In the opinion of the principal investigator, the patient met the 80/80/80% rule during the previous pegylated interferon and ribavirin therapy (ie, received at least 80% of the pegylated interferon and ribavirin doses, at least 80% of the dose size, for at least 80% of the treatment duration) - Willingness to utilize two reliable forms of contraception (for both males and females of childbearing potential) from screening to at least 6 months after the completion of the study	Inclusion Criteria Index	- Hepatitis C virus infection - Subjects with Chronic Hepatitis C Infection - Hepatitis C virus infection - Subjects with Positive Serological Markers for Hepatitis C - Subjects positive for HCV RNA - Hepatitis C virus infection - Subjects with Prior Hepatitis C Therapy - Hepatitis C virus infection - Subjects with Treatment Resistant Disease
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