Clinical trial results:
A Phase 4, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Pharmacokinetics and Safety of Obeticholic Acid in Patients with Primary Biliary Cholangitis and Moderate to Severe Hepatic Impairment

Summary

Results information

Trial information

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Additional study identifiers

Sponsors

Paediatric regulatory details

Results analysis stage

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Subjects enrolled per country

Subjects enrolled per age group

Subject disposition

Recruitment

Pre-assignment

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Arm title	

Arm title	

Number of subjects in period 1		

Period 2	
Arms	
Arm title	

Arm title	

Number of subjects in period 2		

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Primary: Tmax of Total OCA at Week 24	

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Primary: Cmax of Total OCA at Week 30

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Primary: Ctrough of Total OCA at Week 30

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Primary: Cmax of Unconjugated OCA at Week 12

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Primary: Tmax of Unconjugated OCA at Week 12	

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Statistical analyses

Primary: Ctrough of Unconjugated OCA at Week 12	

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Primary: AUC0-24h of Unconjugated OCA at Week 12

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Primary: Cmax of Unconjugated OCA at Week 18

End point values				

Statistical analyses

Primary: Tmax of Unconjugated OCA at Week 18

End point values				

Statistical analyses

Primary: Ctrough of Unconjugated OCA at Week 18

End point values				

Statistical analyses

Primary: AUC0-24h of Unconjugated OCA at Week 18

End point values				

Statistical analyses

Primary: Cmax of Unconjugated OCA at Week 24

End point values				

Statistical analyses

Primary: Tmax of Unconjugated OCA at Week 24

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End point values				

Statistical analyses

Primary: Cmax of Unconjugated OCA at Week 30	

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Statistical analyses

Primary: Tmax of Unconjugated OCA at Week 30	

End point values				

Statistical analyses

Primary: Ctrough of Unconjugated OCA at Week 30

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End point values				

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Primary: Cmax of Unconjugated OCA at Week 48

End point values				

Statistical analyses

Primary: Tmax of Unconjugated OCA at Week 48

End point values				

Statistical analyses

Primary: Ctrough of Unconjugated OCA at Week 48

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Statistical analyses

Primary: AUC0-24h of Unconjugated OCA at Week 48

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Statistical analyses

Primary: Cmax of Glyco-OCA at Week 12

End point values				

Statistical analyses

Primary: Tmax of Glyco-OCA at Week 12

End point values				

Statistical analyses

Primary: Ctrough of Glyco-OCA at Week 12

End point values				

Statistical analyses

Primary: AUC0-24h of Glyco-OCA at Week 12

End point values				

Statistical analyses

Primary: Metabolite to Parent Ratio of AUC-0-24h (MRAUC) of Glyco-OCA at Week 12

End point values				

Statistical analyses

Primary: Metabolite to Parent Ratio of Cmax (MRCmax) of Glyco-OCA at Week 12

End point values				

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End point values				

Statistical analyses

Primary: Tmax of Glyco-OCA at Week 18

End point values				

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Primary: Ctrough of Glyco-OCA at Week 18	

End point values				

Statistical analyses

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Primary: MRCmax of Glyco-OCA at Week 18

End point values				

Statistical analyses

Primary: Cmax of Glyco-OCA at Week 24

End point values				

Statistical analyses

Primary: Tmax of Glyco-OCA at Week 24

End point values				

Statistical analyses

Primary: Ctrough of Glyco-OCA at Week 24

End point values				

Statistical analyses

Primary: AUC0-24h of Glyco-OCA at Week 24	

End point values				

Statistical analyses

Primary: MRAUC of Glyco-OCA at Week 24	

End point values				

Statistical analyses

Primary: MRCmax of Glyco-OCA at Week 24	

End point values				

Statistical analyses

Primary: Cmax of Glyco-OCA at Week 30

End point values				

Statistical analyses

Primary: Tmax of Glyco-OCA at Week 30

End point values				

Statistical analyses

Primary: Ctrough of Glyco-OCA at Week 30

End point values				

Statistical analyses

Primary: AUC0-24h of Glyco-OCA at Week 30

End point values				

Statistical analyses

Primary: MRAUC of Glyco-OCA at Week 30

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Statistical analyses

Primary: MRCmax of Glyco-OCA at Week 30

End point values				

Statistical analyses

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End point values				

Statistical analyses

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Statistical analyses

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Primary: AUC0-24h of Glyco-OCA at Week 48

End point values				

Statistical analyses

Primary: MRAUC of Glyco-OCA at Week 48

End point values				

Statistical analyses

Primary: MRCmax of Glyco-OCA at Week 48

End point values				

Statistical analyses

Primary: Tmax of Tauro-OCA at Week 12

End point values				

Statistical analyses

Primary: Ctrough of Tauro-OCA at Week 12

End point values				

Statistical analyses

Primary: AUC0-24h of Tauro-OCA at Week 12

End point values				

Statistical analyses

Primary: MRAUC of Tauro-OCA at Week 12

End point values				

Statistical analyses

Primary: MRCmax of Tauro-OCA at Week 12

End point values				

Statistical analyses

Primary: Cmax of Tauro-OCA at Week 18	

End point values				

Statistical analyses

Primary: Tmax of Tauro-OCA at Week 18	

End point values				

Statistical analyses

Primary: Ctrough of Tauro-OCA at Week 18

End point values				

Statistical analyses

Primary: AUC0-24h of Tauro-OCA at Week 18

End point values				

Statistical analyses

Primary: MRAUC of Tauro-OCA at Week 18

End point values				

Statistical analyses

Primary: MRCmax of Tauro-OCA at Week 18

End point values				

Statistical analyses

Primary: Cmax of Tauro-OCA at Week 24

End point values				

Statistical analyses

Primary: Tmax of Tauro-OCA at Week 24

End point values				

Statistical analyses

Primary: Ctrough of Tauro-OCA at Week 24

End point values				

Statistical analyses

Primary: AUC0-24h of Tauro-OCA at Week 24	

End point values				

Statistical analyses

Primary: MRAUC of Tauro-OCA at Week 24	

End point values				

Statistical analyses

Primary: MRCmax of Tauro-OCA at Week 24

End point values				

Statistical analyses

Primary: Cmax of Tauro-OCA at Week 30

End point values				

End point values				

Statistical analyses

Primary: Ctrough of Tauro-OCA at Week 30

End point values				

Statistical analyses

Primary: AUC0-24h of Tauro-OCA at Week 30

End point values				

Statistical analyses

Primary: MRAUC of Tauro-OCA at Week 30	

End point values				

Statistical analyses

Primary: MRCmax of Tauro-OCA at Week 30	

End point values				

Statistical analyses

Primary: Cmax of Tauro-OCA at Week 48

End point values				

Statistical analyses

Primary: Tmax of Tauro-OCA at Week 48

End point values				

Statistical analyses

Primary: Ctrough of Tauro-OCA at Week 48

End point values				

Statistical analyses

Primary: AUC0-24h of Tauro-OCA at Week 48

End point values				

Statistical analyses

Primary: MRAUC of Tauro-OCA at Week 48

End point values				

Statistical analyses

Primary: MRCmax of Tauro-OCA at Week 48	

End point values				

Statistical analyses

Primary: Cmax of OCA-glucuronide at Week 12

End point values				

Statistical analyses

Primary: Tmax of OCA-glucuronide at Week 12

End point values				

Statistical analyses

Primary: Ctrough of OCA-glucuronide at Week 12

End point values				

Statistical analyses

Primary: AUC0-24h of OCA-glucuronide at Week 12

End point values				

Statistical analyses

Primary: MRAUC of OCA-glucuronide at Week 12	

End point values				

Statistical analyses

Primary: MRCmax of OCA-glucuronide at Week 12

End point values				

Statistical analyses

Primary: Cmax of OCA-glucuronide at Week 18

End point values				

Statistical analyses

Primary: AUC0-24h of OCA-glucuronide at Week 18	

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Statistical analyses

Primary: MRAUC of OCA-glucuronide at Week 18	

End point values				

Statistical analyses

Primary: MRCmax of OCA-glucuronide at Week 18	

End point values				

Statistical analyses

Primary: Cmax of OCA-glucuronide at Week 24

End point values				

Statistical analyses

Primary: Tmax of OCA-glucuronide at Week 24

End point values				

Statistical analyses

Primary: Ctrough of OCA-glucuronide at Week 24

End point values				

Statistical analyses

Primary: AUC0-24h of OCA-glucuronide at Week 24

End point values				

Statistical analyses

Primary: MRAUC of OCA-glucuronide at Week 24	

End point values				

Statistical analyses

Primary: MRCmax of OCA-glucuronide at Week 24	

End point values				

Statistical analyses

Primary: Cmax of OCA-glucuronide at Week 30	

End point values				

Statistical analyses

Primary: Tmax of OCA-glucuronide at Week 30	

End point values				

Statistical analyses

Primary: Ctrough of OCA-glucuronide at Week 30

End point values				

Statistical analyses

Primary: AUC0-24h of OCA-glucuronide at Week 30

End point values				

Statistical analyses

Primary: MRAUC of OCA-glucuronide at Week 30

End point values				

Statistical analyses

Primary: MRCmax of OCA-glucuronide at Week 30

End point values				

Statistical analyses

Primary: Cmax of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: Tmax of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: Ctrough of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: AUC0-24h of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: MRAUC of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: MRCmax of OCA-glucuronide at Week 48

End point values				

Statistical analyses

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point values				

Statistical analyses

Secondary: Change From Baseline in the Model of End-stage Liver Disease (MELD) Score at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in MELD-Sodium (Na) Score at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Child-Pugh Score at Day 1, Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Number of Participants by Child-Pugh Score Component (Ascites Categories)

End point values				

Statistical analyses

Secondary: Number of Participants by Child-Pugh Score Component (Prothrombin Time Categories)

End point values				

Statistical analyses

Secondary: Number of Participants by Child-Pugh Score Component (Serum Albumin Categories)

End point values				

Statistical analyses

Secondary: Number of Participants by Child-Pugh Score Component (Total Bilirubin Categories)

End point values				

End point values				

Statistical analyses

Secondary: Change From Baseline in Total Bilirubin at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Direct Bilirubin at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Alkaline Phosphatase at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Alanine Aminotransferase at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Aspartate Aminotransferase at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Gamma Glutamyl Transferase at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Prothrombin INR at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Creatinine at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

Secondary: Change From Baseline in Albumin at Weeks 3, 6, 12, 18, 24, 30, 36, 42, and 48; and Extension Months 3, 6, 9, 12, and 15

End point values				

Statistical analyses

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End point values				

Statistical analyses

Secondary: Change From Baseline in Total Bile Acids Concentration at Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Month 3

End point values				

Statistical analyses

Secondary: Change From Baseline in Total Endogenous Bile Acids Concentration at Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Month 3

End point values				

Statistical analyses

Secondary: Change From Baseline in 7α-hydroxy-4-cholesten-3-one (C4) at Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Month 3

End point values				

Statistical analyses

Secondary: Change From Baseline in Fibroblast Growth Factor-19 (FGF-19) Concentrations at Weeks 6, 12, 18, 24, 30, 36, and 48; and Extension Month 3

End point values				

Statistical analyses

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Adverse events information

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More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats