A pilot single arm observational study of sofosbuvir/ledipasvir (200 + 45 mg) in 6- to 12- year old children.

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Abstract

BACKGROUND:
No available data on the use of sofosbuvir/ledipasvir combination in treatment of hepatitis C virus (HCV) infection in children 6- to 12- year old.

AIM:
To assess the safety and efficacy of sofosbuvir plus ledipasvir in children 6- to 12- year old with chronic HCV genotype 4 infection.

METHODS:
This is a pilot prospective single arm observational open-label multicentre study. A total of 20 consecutive eligible chronic HCV infected children, aged from 6- to 12- years were included in this study and treated with a fixed sofosbuvir/ledipasvir combination in half the adult dose (200/45 mg) once daily for 12 weeks. Laboratory tests including virological markers were measured at baseline, 2, 4, 8 and 12 weeks (end of treatment [EOT]), and 12 weeks after end of treatment for sustained virological response 12 (SVR12).

RESULTS:
The intention-to-treat (ITT) SVR12 rate was 19/20 (95%; 95% CI: 76.4%-99.1%).
SVR12 was not assessed in one patient who was lost to follow-up after showing viral negativity at the EOT12. All the remaining 19 patients (100%, 95% CI: 83.18%-100%) who completed the full protocol and follow-up visits achieved SVR12 with normal liver, haematological, and renal function tests and no side effects or fatalities.

CONCLUSIONS:
This pilot study demonstrated that the fixed dose sofosbuvir/ledipasvir combination could be safe and effective treatment in children 6- to 12- years with chronic hepatitis C genotype 4 infection. Our pilot results might encourage larger and multicentre studies in this age group.

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PMID:

29696674