



## Log-Binomial Regression

### 1-Associations of hepatitis C virus (HCV) antibody positivity with opioid, stimulant, and polysubstance injection among people who inject drugs (PWID) in rural US communities

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#### Abstract

Background: People who inject drugs (PWID) in the rural U.S. often inject stimulants, alone or with opioids. The impact of these substance use patterns may influence HCV risk behaviors. This analysis examines the associations of HCV antibody positivity with injecting only opioids, only stimulants (methamphetamine/cocaine), and opioids and stimulants together among rural PWID. Methods: The Rural Opioid Initiative (ROI) consists of eight research sites that enrolled people who use drugs in rural communities in ten U.S. states from 2018 to 2020. This cross-sectional analysis included adult participants who resided in a study area and injected any drug in the past 30 days. The primary outcome was HCV antibody positivity. The exposure of interest was injection drug use classified as only opioids, only stimulants, separate injections of opioids and stimulants, and same-syringe injection of both in the past 30 days. We used multi-variable log-binomial regression with generalized linear mixed models to generate prevalence ratios (P.R.) adjusted for demographics, injection history, health insurance, and substance use treatment. Results: Among 3,084 participants enrolled in the ROI, 1,982 met inclusion criteria. Most participants injected opioids and stimulants in the same syringe (34%) or separately (21%), followed by injecting only stimulants (26%), and injecting only opioids (19%). Half (51%) were HCV antibody positive. Compared to people who injected only stimulants, HCV antibody positivity was more prevalent among people who injected opioids alone (aPR=1.62, 95% CI:(1.29-2.03)), injected both opioids and stimulants separately (aPR=1.61, 95% CI:(1.32-1.95)), and in the same syringe (aPR=1.54, 95% CI:(1.28-1.85)). Conclusion: HCV antibody positivity, indicating prior exposure, was highest among those who had recently injected opioids, alone or with stimulants. Additional nucleic acid testing is necessary to confirm active infection. More research is needed to determine the underlying causes of HCV antibody positivity by injection use.

#### Keywords

##### Author Keywords

[Polysubstance use](#)[Injection drug use](#)[Rural](#)[HCV](#)[Opioids](#)[Stimulants](#)

##### Keywords Plus

[UNITED-STATES](#)[SUBSTANCE USE](#)[INFECTION](#)[OVERDOSE](#)[USERS](#)[PREVALENCE](#)[BEHAVIORS](#)[INCREASES](#)[RISE](#)

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### 2-Intracytoplasmic sperm injection versus conventional in-vitro fertilisation for couples with infertility with non-severe male factor: a multicentre, open-label, randomised controlled trial

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#### Abstract

**Background** Introduced in 1992, intracytoplasmic sperm injection (ICSI) was initially indicated for severe male infertility; however, its use has since been expanded to non-severe male infertility. We aimed to compare the efficacy and safety of ICSI versus conventional in-vitro fertilisation (IVF) in couples with infertility with non-severe male factor. **Methods** We conducted an investigator-initiated, multicentre, open-label, randomised controlled trial in ten reproductive medicine centres across China. Couples with infertility with non-severe male factor without a history of poor fertilisation were randomly assigned (1:1) to undergo either ICSI or conventional IVF. The primary outcome was live birth after first embryo transfer. We performed the primary analysis in the intention-to-treat population using log-binomial regression models for categorical outcomes or linear regression models for continuous outcomes, adjusting for centre. This trial is registered with Clinicaltrials.gov, NCT03298633, and is completed. **Findings** Between April 4, 2018, and Nov 15, 2021, 3879 couples were screened, of whom 2387 (61 center dot 5%) couples were randomly assigned (1184 [49 center dot 6%] to the ICSI group and 1203 [50 center dot 4%] to the conventional IVF group). After excluding couples who were ineligible, randomised twice, or withdrew consent, 1154 (97 center dot 5%) in the ICSI group and 1175 (97 center dot 7%) in the conventional IVF group were included in the primary analysis. Live birth after first embryo transfer occurred in 390 (33 center dot 8%) couples in the ICSI group and in 430 (36 center dot 6%) couples in the conventional IVF group (adjusted risk ratio [RR] 0 center dot 92 [95% CI 0 center dot 83-1 center dot 03];  $p=0$  center dot 16). Two (0 center dot 2%) neonatal deaths were reported in the ICSI group and one (0 center dot 1%) in the conventional IVF group. **Interpretation** In couples with infertility with non-severe male factor, ICSI did not improve live birth rate compared with conventional IVF. Given that ICSI is an invasive procedure associated with additional costs and potential increased risks to offspring health, routine use is not recommended in this population.

#### Keywords

#### Keywords Plus

[WORLD-HEALTH-ORGANIZATIONSIBLING OOCYTESREPRODUCTIVE TECHNOLOGIESICSIIVFGUIDELINESOUTCOMESINSEMINATIONASSOCIATIONMORPHOLOGY](#)

### 3-Effect of Testosterone on Progression From Prediabetes to Diabetes in Men With Hypogonadism - A Substudy of the TRAVERSE Randomized Clinical Trial

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#### Abstract

**Importance** The effect of testosterone replacement therapy (TRT) in men with hypogonadism on the risk of progression from prediabetes to diabetes or of inducing glycemic remission in those with diabetes is unknown. **Objective** To evaluate the efficacy of TRT in preventing progression from prediabetes to diabetes in men with hypogonadism who had prediabetes and in inducing glycemic remission in those with diabetes. **Design, Setting, and Participants** This nested substudy, an intention-to-treat analysis, within a placebo-controlled randomized clinical trial (Testosterone Replacement Therapy for Assessment of Long-Term Vascular Events and Efficacy Response in Hypogonadal Men [TRAVERSE]) was conducted at 316 trial sites in the US. Participants included men aged 45 to 80 years with hypogonadism and prediabetes or diabetes who were enrolled in TRAVERSE between May 23, 2018, and February 1, 2022. **Intervention** Participants were randomized 1:1 to receive 1.62% testosterone gel or placebo gel until study completion. **Main Outcomes and Measures** The primary end point was the risk of progression from prediabetes to diabetes, analyzed using repeated-measures log-binomial regression. The secondary end point was the risk of glycemic remission (hemoglobin A1c level <6.5% [to convert to proportion of total hemoglobin, multiply by 0.01] or 2 fasting glucose measurements <126 mg/dL [to convert to mmol/L, multiply by 0.0555] without diabetes medication) in men who had diabetes. **Results** Of 5204 randomized participants, 1175 with prediabetes (mean [SD] age, 63.8 [8.1] years) and 3880 with diabetes (mean [SD] age, 63.2 [7.8] years) were included in this study. Mean (SD) hemoglobin A1c level in men with prediabetes was 5.8% (0.4%). Risk of progression to diabetes did not differ significantly between testosterone and placebo groups: 4 of 598 (0.7%) vs 8 of 562 (1.4%) at 6 months, 45 of 575 (7.8%) vs 57 of 533 (10.7%) at 12 months, 50 of 494 (10.1%) vs 67 of 460 (14.6%) at 24 months, 46 of 359 (12.8%) vs 52 of 330 (15.8%) at 36 months, and 22 of 164 (13.4%) vs 19 of 121 (15.7%) at 48 months (omnibus test  $P = .49$ ). The proportions of participants with diabetes who experienced glycemic remission and the changes in glucose and hemoglobin A1c levels were similar in testosterone- and placebo-treated men with prediabetes or diabetes. **Conclusions and Relevance** In men with hypogonadism and prediabetes, the incidence of progression from prediabetes to diabetes did not differ significantly between testosterone- and placebo-treated men. Testosterone replacement therapy did not improve glycemic control in men with hypogonadism and prediabetes or diabetes. These findings suggest that TRT alone should not be used as a therapeutic intervention to prevent or treat diabetes in men with hypogonadism.

#### Keywords

#### Keywords Plus



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[ENDOGENOUS SEX-HORMONES](#)[FASTING PLASMA-GLUCOSE](#)[HYPOGONADOTROPIC](#)  
[HYPOGONADISM](#)[INSULIN-RESISTANCE](#)[HEMOGLOBIN A\(1C\)](#)[BODY-COMPOSITION](#)[NATIONAL-](#)  
[HEALTH](#)[PREVALENCE](#)[THERAPY](#)[RISK](#)