Tenofovir/Emtricitabine Bioequivalence Following Ingestible Sensor Co-encapsulation

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Conflict of Interest

None to disclose
Adherence in YMSM

• MSM account for 70% of all new HIV infections
  – 27% of new infections in YMSM 13-24 years

• Young age is correlated with lower adherence
  – iPrex demonstrated lower PrEP efficacy (28%) in YMSM compared to older participants (56%)

Koss et al. 2017
Current Approaches

• Limitations in current methods: lack of precision, “white-coat adherence”, dependence upon patient participation/engagement, and difficult implementation

• TFV-DP concentrations

• Proteus Discover
How Proteus Discover Works

The sensor sends a signal to the patch as it passes through the stomach.

The patch sends this information to the app along with records of steps, activity rest and heart rate.

The app allows patients to see how they are doing and share this with their healthcare team via the portal.

Wearable patch

Discover app

Discover portal

Used by patients

Used by healthcare teams

DigiMeds™
A tiny sensor is placed inside a small pill.

The sensor contains tiny amounts of silicon, copper and magnesium that pass through the body naturally, just like the fiber in food.
Study Objective

Determine bioequivalence between TDF/FTC encapsulated with ingestible sensor versus unencapsulated TDF/FTC
# Methods

- Randomized, cross-over study of 24 participants

<table>
<thead>
<tr>
<th>Day</th>
<th>0</th>
<th>14</th>
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<tbody>
<tr>
<td>Dose</td>
<td>72 hours</td>
<td>72 hours</td>
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- Non-compartmental analysis of AUC, $C_{\text{max}}$ and $t_{1/2}$
Bioequivalence is defined as the 90% confidence interval (CI) of geometric mean ratio of AUC and $C_{\text{max}}$ being within 80%-125%.
### Patient Demographics

<table>
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<tr>
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<th>N=24</th>
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<tbody>
<tr>
<td><strong>Sex, n(%)</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (46%)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (54%)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity, n(%)</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>19 (79%)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (13%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>2 (8%)</td>
</tr>
<tr>
<td><strong>Age (yr), mean ± SD</strong></td>
<td>28 ± 4</td>
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<tr>
<td><strong>Weight (kg), mean ± SD</strong></td>
<td>74 ± 14</td>
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Plasma TFV and FTC after encapsulation with ingestible sensor

Tenofovir

Emtricitabine
Bioequivalence: GMR ratio between 80-125%
Conclusions

Bioequivalence has been confirmed for TDF/FTC co-encapsulated with the Proteus® ingestible sensor

1) Confirms medication ingestion

2) Smartphone interface that captures temporal adherence patterns

3) Real-time feedback of validated and population-specific HIV risk reduction education and health promotion

4) Use for future PrEP studies
Future Directions

• Feasibility and Acceptability Study
  – Cross-over study of 12 weeks dosing with and without ingestible sensor
  – Qualitatively explore acceptability
  – Adherence as measured by TFV-DP levels in DBS will be compared to adherence detected by ingestible sensor and self-report
Challenges in Digital Medicine

• Adherence to patch

• Psychological factors rather than “forgetting”

• Cost

• Privacy Concerns
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