

When to start antiretroviral treatment in a patient with a recent diagnosis of HIV infection?

I would start the treatment immediately

Dr. Antonio Rivero  
Hospital Universitario Reina Sofía

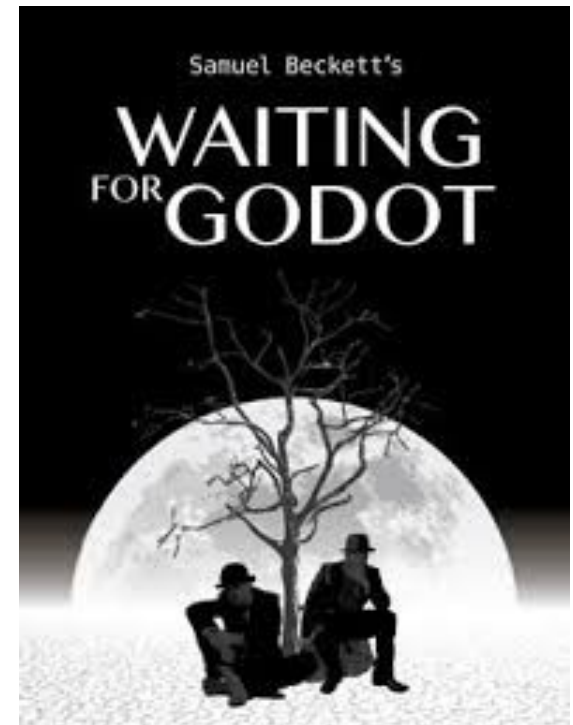
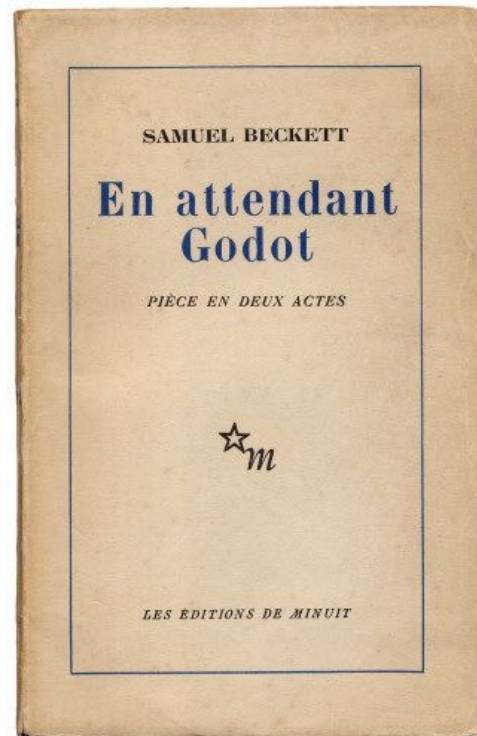
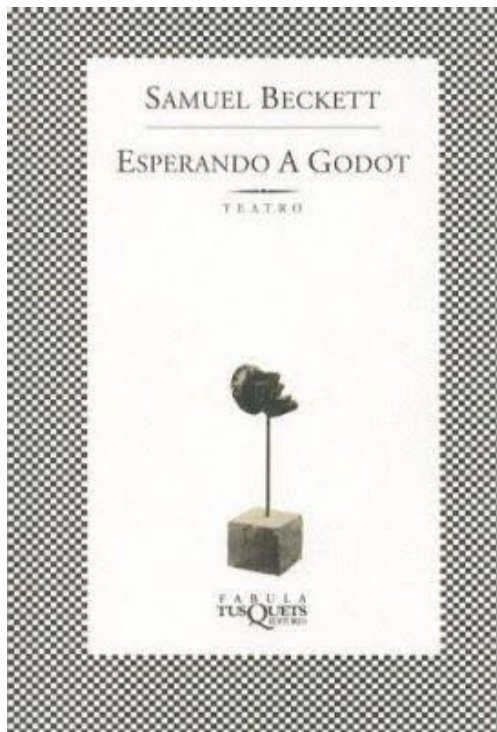
# Conflictos de Interés

- ARR ha recibido honorarios por participar en actividades formativas y/o de asesoramiento de VIIV, Gilead, Janssen, Celgene, MSD y Abbvie.

# Samuel Beckett: Premio Nobel de literatura 1969



# “Esperando a Godot”



# “Esperando a Godot”



# “Esperando a Godot”



**ESTRAGON:** Vayámonos.

**VLADIMIR:** No podemos.

**ESTRAGON:** ¿Por qué?

**VLADIMIR:** Estamos esperando a Godot.

# “Esperando a Godot”

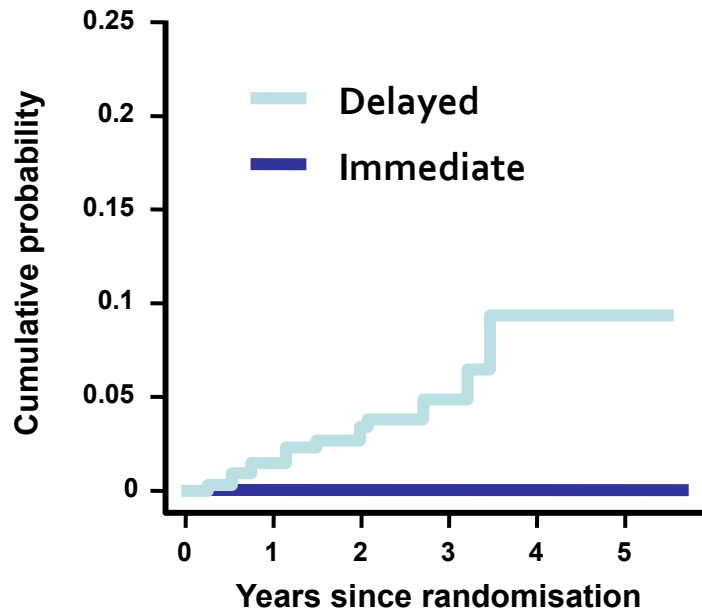


**ESTRAGON:** Vayámonos.  
**VLADIMIR:** No podemos.  
**ESTRAGON:** ¿Por qué?  
**VLADIMIR:** Estamos esperando a Godot.

# ¿Por que no debemos diferir el TAR?

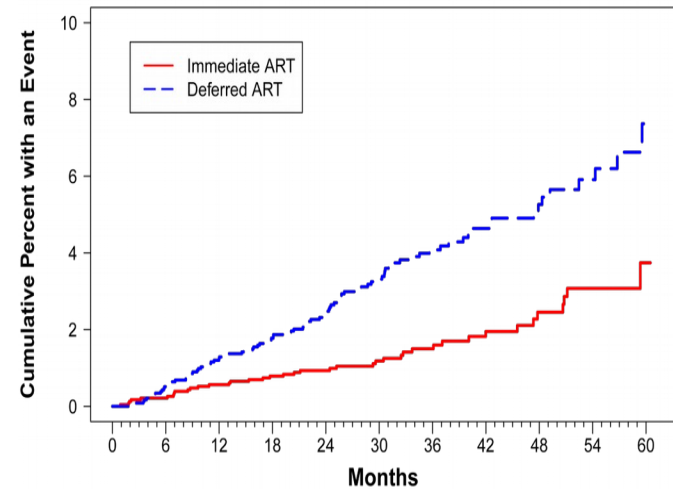
**HPTN 052: TAR Inmediato disminuye el riesgo de transmisión**

**Linked HIV transmission**



No. at risk	0	1	2	3	4	5
Immediate	893	658	298	79	31	24
Delayed	882	655	297	80	26	22

**START: TAR Inmediato mejora pronóstico de pacientes**



Type of event	Imm. ART	Def. ART
Serious AIDS	14	50
Serious non-AIDS	29	47
Total*	42	96



# ¿Que debatimos?

En la Primera visita clínica de un paciente con diagnostico de infección por VIH (diagnostico confirmado: Serología positiva + confirmación serológica o virológica)

Dr. Pineda

Diferir el TAR  
“pero poquito”

Dr. Rivero

No Diferir el TAR

# ¿Que debatimos?

En la Primera visita clínica de un paciente con diagnostico de infección por VIH (diagnostico confirmado: Serología positiva + confirmación serológica o virológica)

Dr. Pineda

Dr. Rivero

Iniciemos TAR.

No podemos.

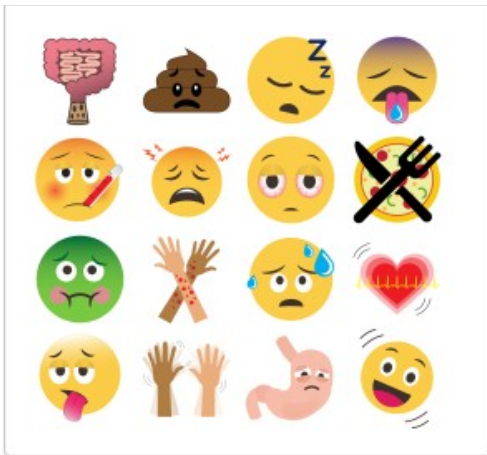
¿Por qué?

¡Porque hay que esperar a Godot!

## Documento de consenso del tratamiento antiretroviral en adultos infectados por el VIH (Version 2014)

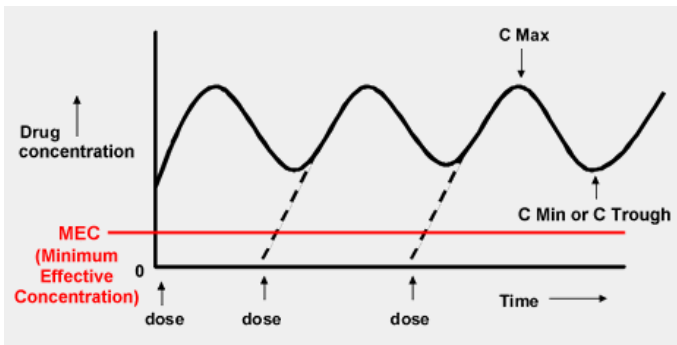
- Se recomienda TAR **en todos los pacientes con infección por el VIH** para evitar la progresión de la enfermedad, disminuir la transmisión del virus y limitar el efecto nocivo sobre posibles morbilidades coexistentes (A-I).
- El inicio del TAR debe valorarse siempre individualmente. **Antes de tomar la decisión de iniciarlo deben confirmarse las cifras de linfocitos CD4+ y CVP. Además, debe prepararse al paciente**, ofertando las distintas opciones, adaptando el esquema terapéutico al estilo de vida, comorbilidades, posibles interacciones **y valorando el riesgo de mala adherencia** (A-III)

# Recomendación inspirada en escenarios pasados de gran peso



Problema	Perfil
Efectos adversos	Altos/Graves
Nº Comprimidos	Muy alto
Conveniencia	Muy baja
Interacciones	Alto riesgo
Eficacia TAR (ITT)	<70%
TAR Universal	No
Inicio de TAR	Riesgo/beneficio

## INTERACCIONES MEDICAMENTOSAS

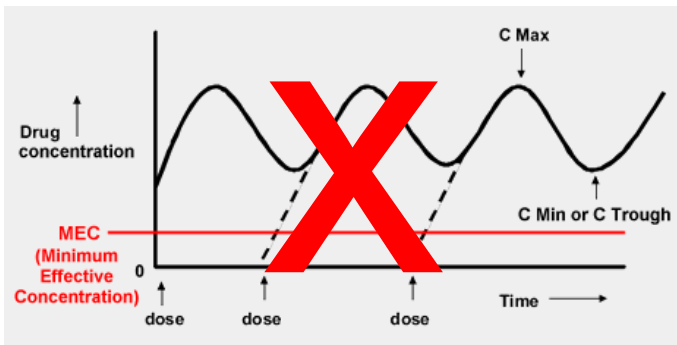


# Recomendación inspirada en escenarios pasados de gran peso



Problema	Perfil
Efectos adversos	<b>Muy Bajo</b>
Nº Comprimidos	<b>Minimo (1)</b>
Conveniencia	<b>Muy alta (QD)</b>
Interacciones	<b>Baja</b>
Eficacia TAR (ITT)	<b>90%</b>
TAR Universal	<b>Si</b>
Inicio de TAR	<b>Siempre</b>

INTERACCIONES MEDICAMENTOSAS



# Justificación para diferir el tratamiento tras diagnóstico

1. Esperar datos complementarios: Optimizar el TAR:
  - *Cifras de CD4 y Carga viral del VIH*
  - *Usar ABC en TAR (HLA-B 5701)*
  - *Poder disponer de Test VHB (FTC/TAF)*
  - *Poder disponer de Test TB (implicaciones TAR)*
  - *Poder disponer test Resistencia*
  - *Más opciones terapéuticas*
  - *Más tiempo para considerar las opciones.*
2. Mayor compromiso del paciente antes de iniciar el TAR
  - *Evitar presiones*
  - *Tiempo para asimilar el diagnóstico.*
  - *Construir una relación más fuerte para el futuro.*
3. Medida sin beneficio que incluso puede resultar negativa
4. Falta de evidencia

# Justificación para diferir el tratamiento tras diagnóstico

- 1. Esperar datos complementarios: Optimizar el TAR**
  - *Cifras de CD4 y CVP.*
  - *Usar ABC en TAR (HLA-B 5701)*
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  - *Evitar presiones*
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  - *Construir una relación más fuerte para el futuro.*
- 3. Medida sin beneficio que incluso puede resultar negativa**

# Realmente ¿que es imprescindible para iniciar TAR?

- Valoración Clínica
- Bioquímica

- Carga Viral VIH (?)
- CD4+
- Resistencias VIH
- HLAB5701
- Genotipo VIH
- VHA, VHB, VHC
- Serología (Toxo, ITS...)
- PPD/IGRA
- RxT
- ECG

**No es imprescindible esperar los resultados de una prueba si se utiliza un régimen de TAR cuyo uso no esté condicionado a sus valores (incluyendo CV y CD4)**



# ¿Con que regímenes de TAR no podríamos comenzar el mismo día?

Si no dispusiéramos HLAB5701

ABC

ABC/3TC/DTG\*

Si no dispusiéramos de CD4+

DTG/3TC

Si no dispusiéramos de carga viral

RILPIVIRINA

¿Con que regimen podríamos comenzar el mismo dia?

FTC/TAF

```
graph TD; A[FTC/TAF] --- B[DTG]; A --- C[RAL]; A --- D[BIC]; A --- E[DRV];
```

DTG

RAL

BIC

DRV

Podríamos comenzar el mismo día con la mayoría de las pautas preferentes/alternativas

las exploraciones complementarias no condicionan el uso de la mayoría de regímenes...

**¿Tenemos que esperar a GODOT?**



# Justificación para diferir el tratamiento tras diagnóstico

## 1. Esperar datos complementarios: Optimizar el TAR:

- *Cifras de CD4 y CVP.*
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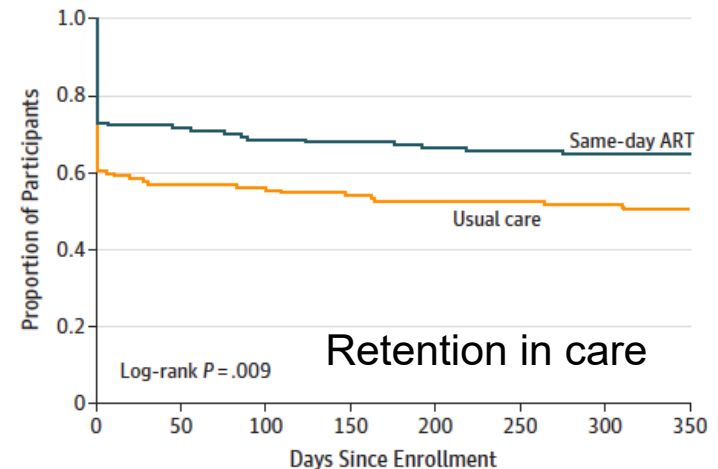
## 2. Conseling: Mayor compromiso del paciente y adherencia

- *Evitar presiones*
- *Tiempo para asimilar el diagnóstico.*
- *Construir una relación más fuerte para el futuro.*

## 3. Medida sin beneficio que incluso puede resultar negativa

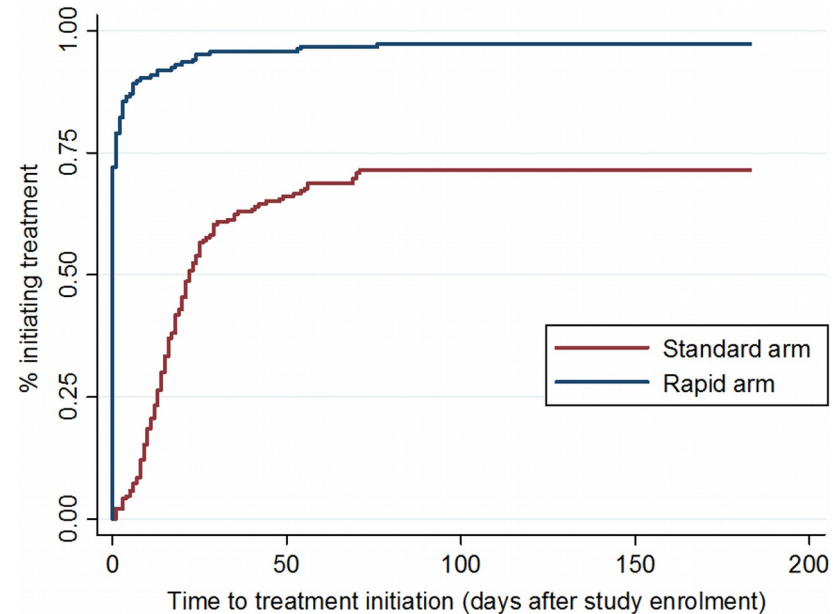
# Cascade Clinical Trial

- **Diseño:** Randomizado, abierto
  - TAR inmediato (mismo día)
  - TAR Standard (2ª visita con análisis y counseling)
- **Area:** Lesotho
- **End point primario:**
  - Linkage to care a los 3 meses
  - ARN-VIH < 100 cop a 12 meses
- **Numero:** 278 pacientes



# RAPIT: Inicio de TAR en primera visita

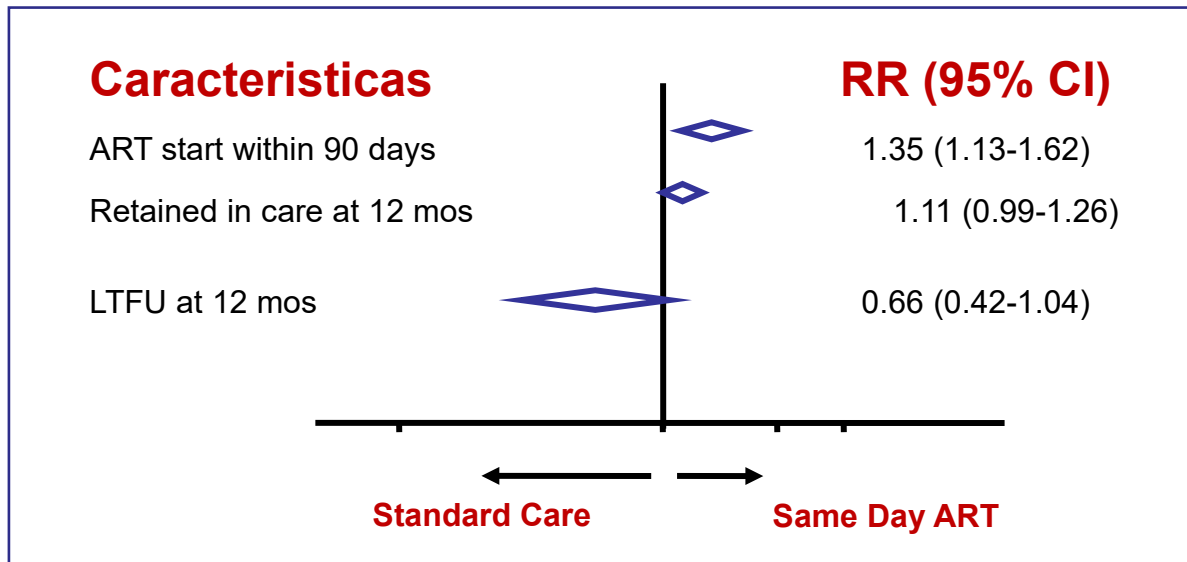
- + Sudafrica
- + EC aleatorizado a iniciar TAR:
  - En primera visita (RAPID)
  - Standard (3-5 visitas durante 2-4 w)
- + End point: ARN-VIH <400 a los 10 meses y adhesión al seguimiento



Outcome	Standard arm(%) n = 190	Rapid arm(%) n = 187	Crude risk difference (95% CI)	Crude relative risk (95% CI)
Initiated $\leq$ 90 d and suppressed by 10 mo (primary outcome)	96 (51%)	119 (64%)	13% (3%–23%)	1.26 (1.05–1.50)

# Metanálisis de 4 EECC

- Origen: Africa, Haiti
- Standard of care vs Inicio en el mismo día del diagnóstico



Si diferir el TAR para conseling no mejora la adhesión al tratamiento/seguimiento (evidencias de lo contrario)...

**¿Tenemos que esperar a GODOT?**



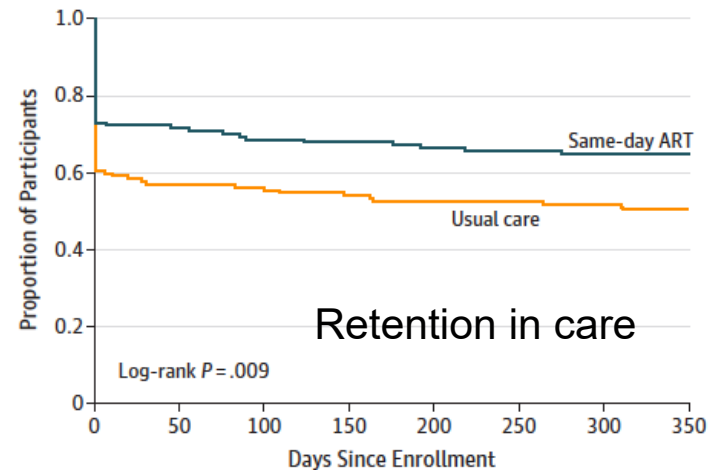


# Justificación para diferir el tratamiento tras diagnóstico

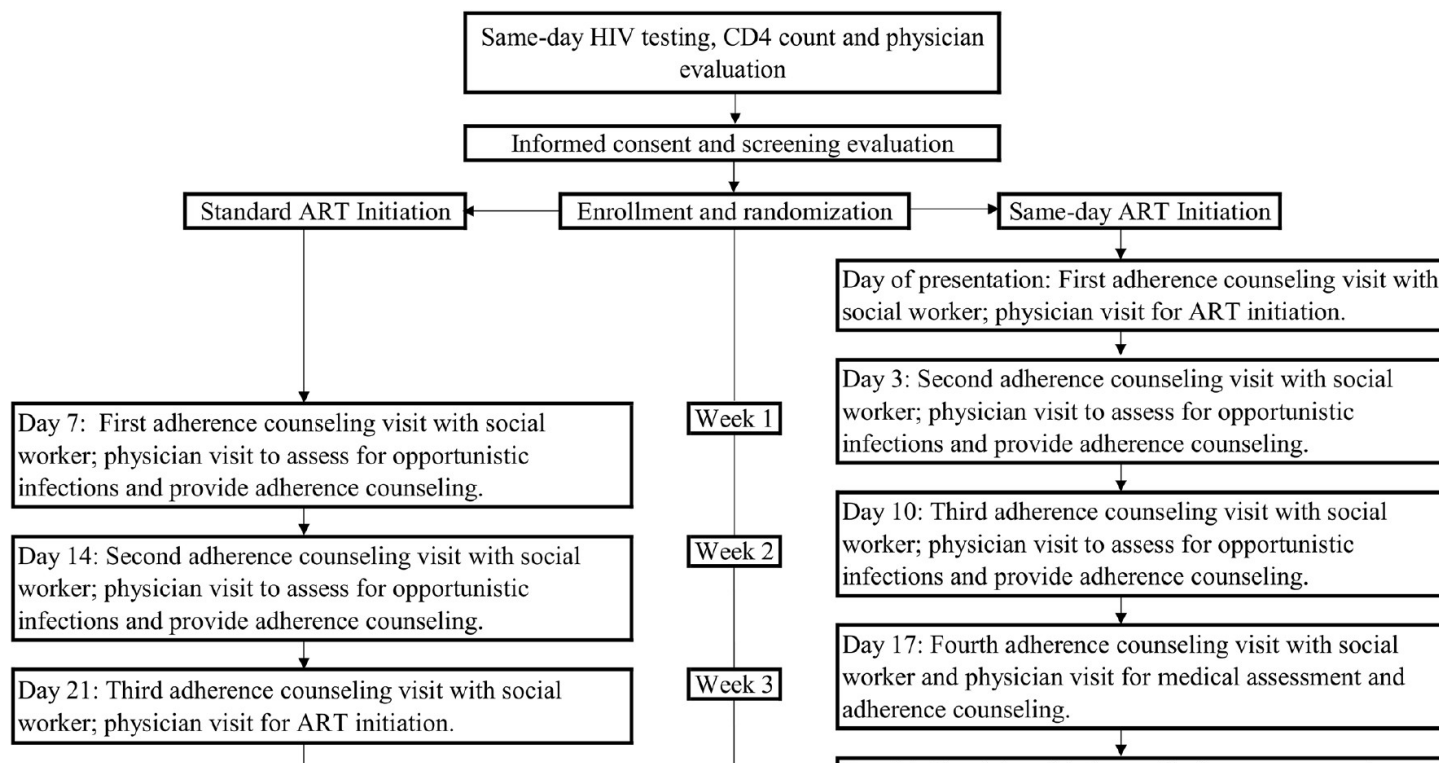
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3. **Medida sin beneficio que incluso puede resultar negativa**

# Cascade Clinical Trial

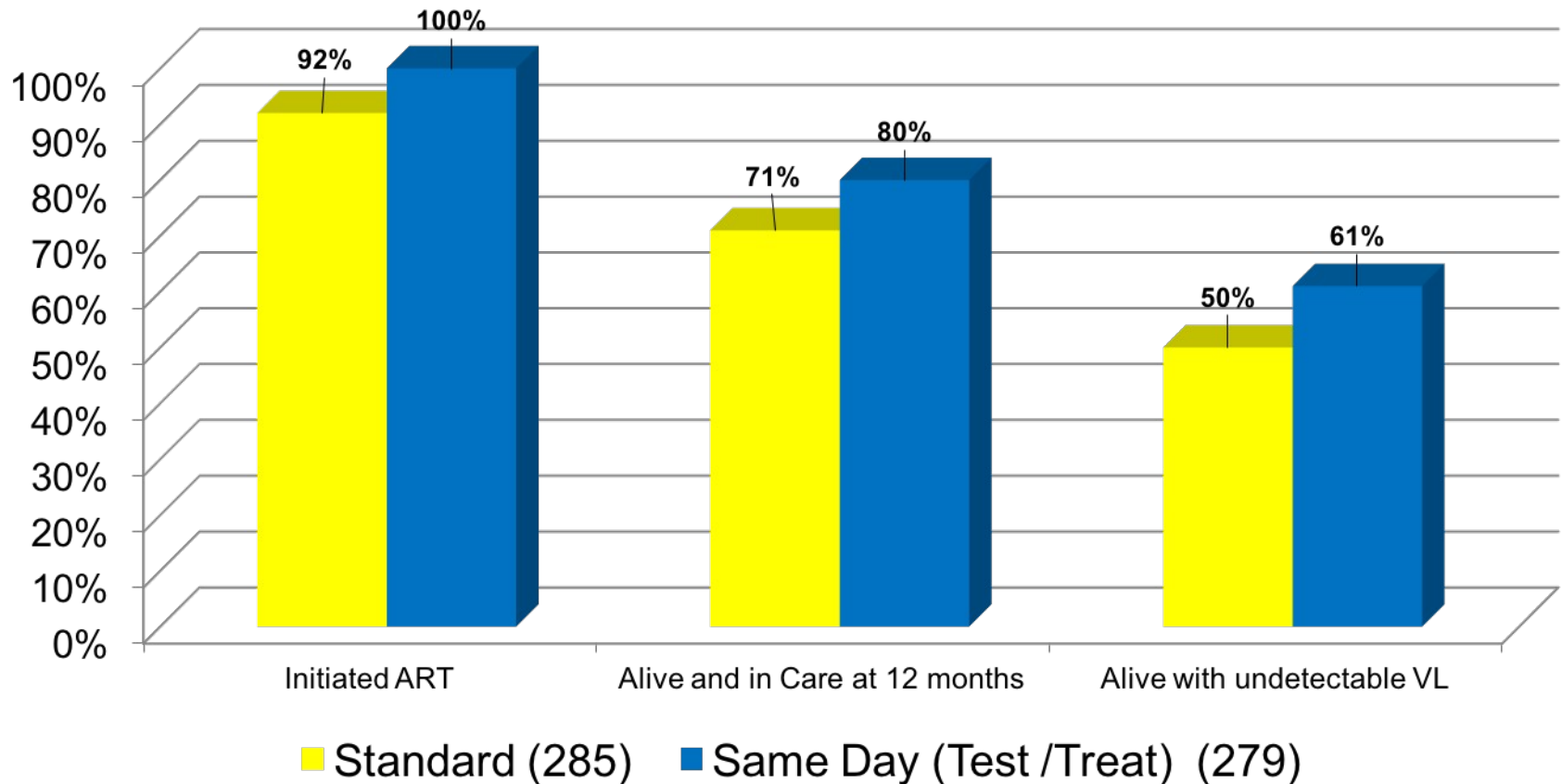
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- **End point primario:**
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  - ARN-VIH < 100 cop a 12 meses
- **Numero:** 278 pacientes



# GHESKIO/HARVARD: Inicio TAR standard ART versus Inmediato (mismo dia del diagnóstico).

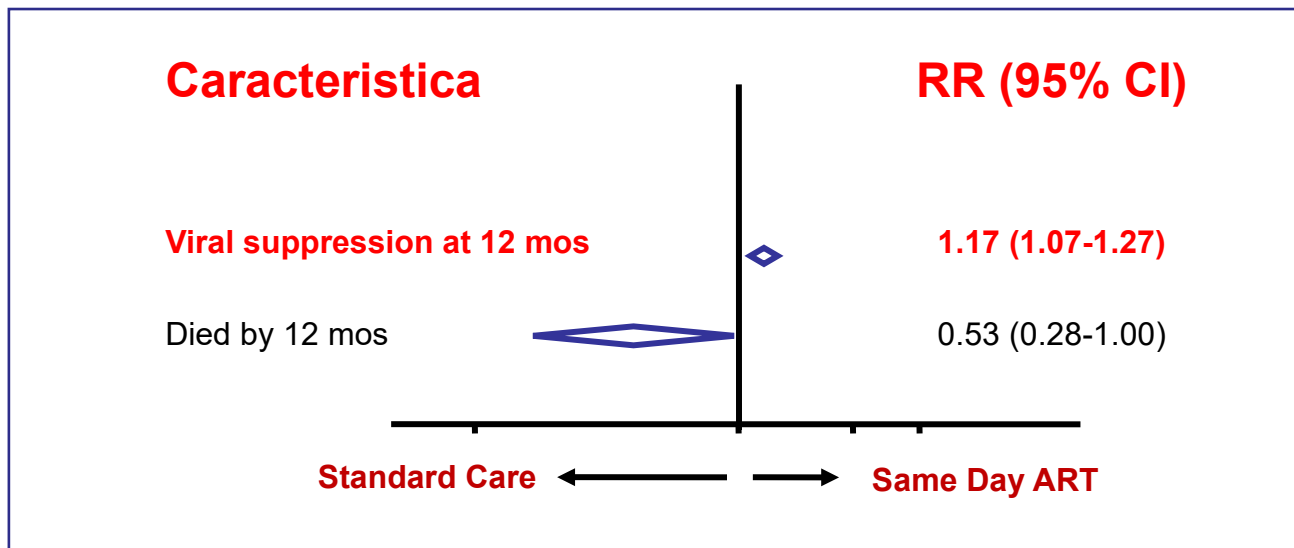


# GHESKIO/HARVARD: Standard vs. Inmediato Situación a los 12 meses



# Metanálisis de 4 EECC

- Origen: Africa, Haiti
- Standard of care vs Inicio en el mismo día del diagnóstico



Si las evidencias sugieren que el TAR inmediato como estrategia es mas eficaz en conseguir ARN-VIH indetectable a largo plazo...

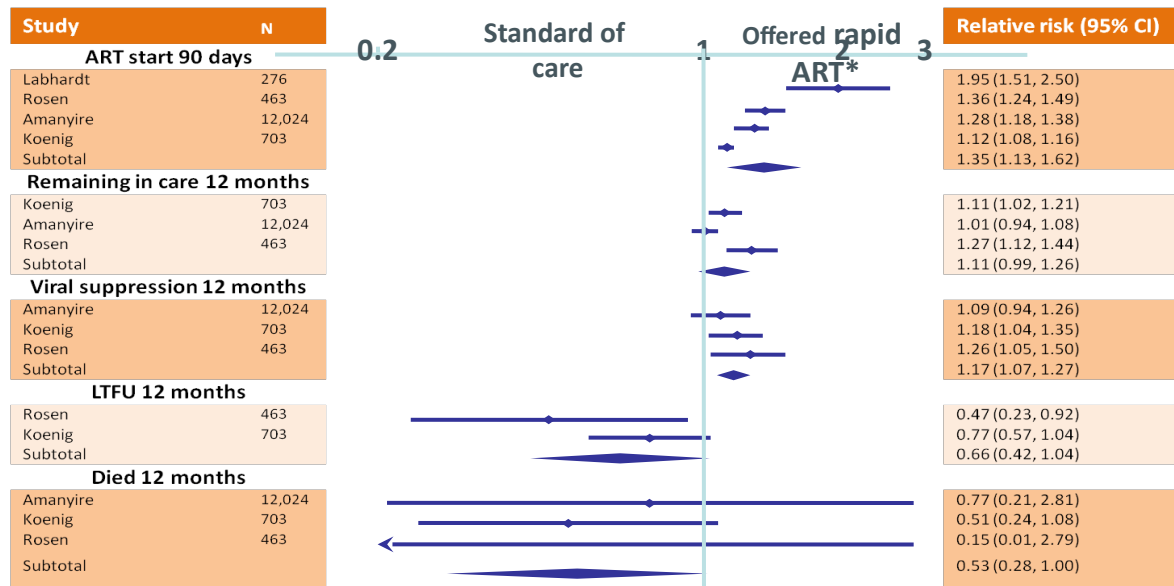
**¿Tenemos que esperar a GODOT?**



# Justificación para diferir el tratamiento tras diagnóstico

1. Esperar datos complementarios: Optimizar el TAR:
2. Mayor compromiso del paciente antes de iniciar el TAR
3. Medida sin beneficio que incluso puede resultar negativa
4. **No hay evidencia. Y la que hay procede de países en desarrollo**

# Evidencias: 4 Ensayos clínicos randomizados + 1 metanálisis





# Evidencias en países en desarrollo: 3 estudios observacionales y un Ensayo clínico

## SCIENTIFIC REPORTS

### OPEN Rapid HIV Viral Load Suppression in those Initiating Antiretroviral Therapy at First Visit after HIV Diagnosis

Received: 17 June 2016  
Accepted: 18 August 2016  
Published: 06 September 2016

Martin Hoengig<sup>1,2,3</sup>, Antoine Chailion<sup>1</sup>, David J. Moore<sup>4</sup>, Sheldon R. Morris<sup>5</sup>, Sanjay R. Mehta<sup>1,3</sup>, Sara Gianella<sup>6</sup>, G. Brett Amico<sup>7</sup> & Susan A. Little<sup>8</sup>

**Expert guidelines for antiretroviral therapy (ART) now recommend ART as soon as possible in all HIV infected persons to reduce the risk of disease progression and prevent transmission. The goal of this observational study was to evaluate the impact of very early ART initiation and regimen type on time to viral suppression. We evaluated time to viral suppression among 86 persons with newly diagnosed HIV infection who initiated ART within 30 days of diagnosis. A total of 36 (42%) had acute, 27 (31%) early, and 23 (27%) had established HIV infection. The median time from an offer of immediate ART to starting ART was 8 days. A total of 56 (65%) initiated an integrase inhibitor-based regimen and 30 (35%) a protease inhibitor-based regimen. The time to viral suppression was significantly shorter in those receiving an integrase inhibitor versus a protease inhibitor-based regimen ( $p = 0.022$ ). Twenty-two (26%) initiated ART at their HIV care intake visit and 73% of those participants achieved viral suppression at week 2, 82% at week 26 and 96% at week 54. ART initiated at the intake visit led to rapid and reliable viral suppression in acute, early and chronic HIV infection, in particular when integrase inhibitor-based regimens were used.**

Despite intense efforts to diagnose HIV infection as early as possible, engage newly-diagnosed individuals into care, and recommend antiretroviral therapy (ART) for all infected persons<sup>1,2</sup>, HIV incidence still remains stable in the United States, and is increasing among men who sex with men (MSM)<sup>3,4</sup>. Universal treatment as prevention (U=PrE) is one of the most promising strategies to reduce HIV incidence<sup>5,6</sup>. U=PrE may be particularly effective when initiated during acute HIV infection (AHI), which is associated with transient levels of extremely high viral viraemia<sup>7,8</sup>. AHI therefore serves as a major driver of HIV transmission in sexually active populations, and in particular among MSM in the United States and other resource-rich countries<sup>9,10</sup>. As many as half of HIV transmissions occur from persons with AHI<sup>11</sup>. Very early initiation of ART in AHI may rapidly decrease viral loads and therefore reduce infectiousness during this particularly important period. There is also consistent evidence that very early ART may benefit the individual infected with HIV by leading to more rapid and robust immunologic recovery, lower inflammation and reduced viral reservoir size compared to a later start<sup>12</sup>. ART as early as possible after diagnosis improves mortality and morbidity in all stages of HIV infection<sup>13</sup>. Expert guidelines for ART therefore now recommend ART as soon as possible, regardless of CD4 cell count, to reduce the risk of disease progression and prevent HIV transmission<sup>14</sup>. Limited data exist, however, on the uptake and barriers to the initiation of very early ART, in particular about ART delivered as early as the day an individual is informed about their HIV diagnosis. Importantly, newly HIV diagnosed persons are faced with negotiating a complex healthcare system while coping with acute negative reactions (e.g., fear, anxiety, depression, stigma

<sup>1</sup>Division of Infectious Diseases, Department of Medicine, University of California San Diego, San Diego, California, United States. <sup>2</sup>Section of Infectious Diseases and Tropical Medicine, Department of Internal Medicine, Medical University of Graz, Graz, Austria. <sup>3</sup>Division of Pulmonology, Department of Internal Medicine, Medical University of Graz, Graz, Austria. <sup>4</sup>Department of Psychiatry, University of California San Diego (UCSD), La Jolla, California, United States. <sup>5</sup>Veterans Affairs Healthcare System, San Diego, California, United States. <sup>6</sup>Department of Health Behavior and Society, School of Public Health, University of Michigan, Ann Arbor, MI, USA. Correspondence and requests for materials should be addressed to M.H. (email: hoengig@ucsd.edu).

SAN DIEGO

Hoengig M et al,  
Sci Rep, 2016

## CLINICAL SCIENCE

### The Effect of Same-Day Observed Initiation of Antiretroviral Therapy on HIV Viral Load and Treatment Outcomes in a US Public Health Setting

Christopher D. Pilcher, MD<sup>1</sup>, Clarissa Ospina-Norwell, FN-P<sup>2\*</sup>, Aditi Dasgupta, BS<sup>1</sup>, Diane Jones, RN<sup>1\*</sup>, Wendy Hartogensis, PhD<sup>1</sup>, Sandra Torres, MSW<sup>1</sup>, Fabiola Calderon, MSW<sup>1</sup>, Erin Domico, MPH<sup>1</sup>, Elvin Geng, MD<sup>1</sup>, Monica Gandhi, MD<sup>1</sup>, Diane V. Havir, MD<sup>1</sup>, and Hiroyo Hatano, MD<sup>1</sup>

**Background:** Antiretroviral therapy (ART) is typically begun weeks after HIV diagnosis. We assessed the acceptability, feasibility, safety, and efficacy of initiating ART on the same day as diagnosis.

**Methods:** We studied a clinician-based cohort consisting of consecutive patients who were referred with new HIV diagnosis between June 2013 and December 2014. A subset of patients with acute or recent infection (<6 months) or CD4 <200 were managed according to a “RAPID” care initiation protocol. An intensive, same-day appointment included social needs assessment, medical provider evaluation, and a first ART dose offered after laboratories were drawn. Patient acceptance of ART, drug toxicities, drug resistance, and time to viral suppression outcomes were compared between RAPID participants and contemporaneous patients (who were not offered the program), and with an historical cohort.

**Results:** Among 86 patients, 39 were eligible and managed on the RAPID protocol. Thirty-seven (94.9%) of 39 in RAPID began ART within 24 hours. Minor toxicity with the initial regimen occurred in 2 (5.1%) of intervention patients versus none in the nonintervention group. Loss to follow-up was similar in intervention (10.3%) and nonintervention patients (14.9%) during the study. Time to virologic suppression (<200 copies HIV RNA/mL) was significantly faster (median 1.8 months) among intervention-managed patients when compared with patients treated in the same clinic under prior recommendations for universal ART (4.3 months;  $P = 0.0001$ ).

Received for publication May 5, 2016; accepted June 17, 2016. From the <sup>1</sup>Department of Medicine, Division of HIV, Infectious Diseases and Global Medicine, University of California, San Francisco, CA, and <sup>2</sup>Yale University School of Medicine, New Haven, CT, USA. Supported by a grant from the NINDS/NIAID R01NS096606 (C.D.P.). The remaining authors have no funding or conflicts of interest to disclose. **Partial results previously presented at:** C.D.P. et al. *Providing same-day observed ART to newly diagnosed HIV seropositive is associated with improved virologic suppression.* *16th International AIDS Society Conference on HIV Pathogenesis, Treatment, and Prevention (IAS 2015), July 19–22, 2015, Vancouver, Canada (abstract WAB02018).* Correspondence to: Christopher D. Pilcher, MD, Department of Medicine, Division of HIV, Infectious Diseases and Global Medicine, University of California, San Francisco, Box 0874, San Francisco General Hospital, Ward 86, 995 Pomeroy Avenue, San Francisco, CA 94143-0874 (email: cpilcher@peds.ucsf.edu). Copyright © 2016 Wolters Kluwer Health, Inc. All rights reserved.

44 | www.jaids.com

J Acquir Immune Defic Syndr • Volume 74, Number 1, January 1, 2017

SAN FRANCISCO

Pilcher et al,  
Antivir Ther, 2017

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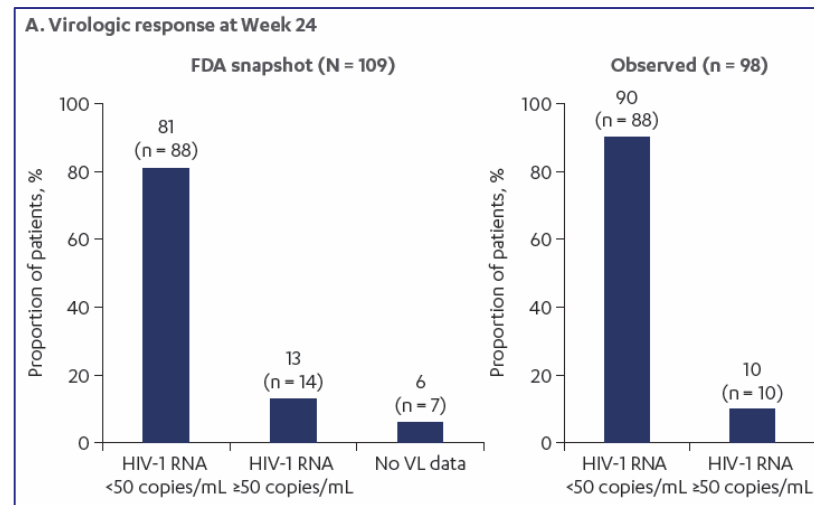
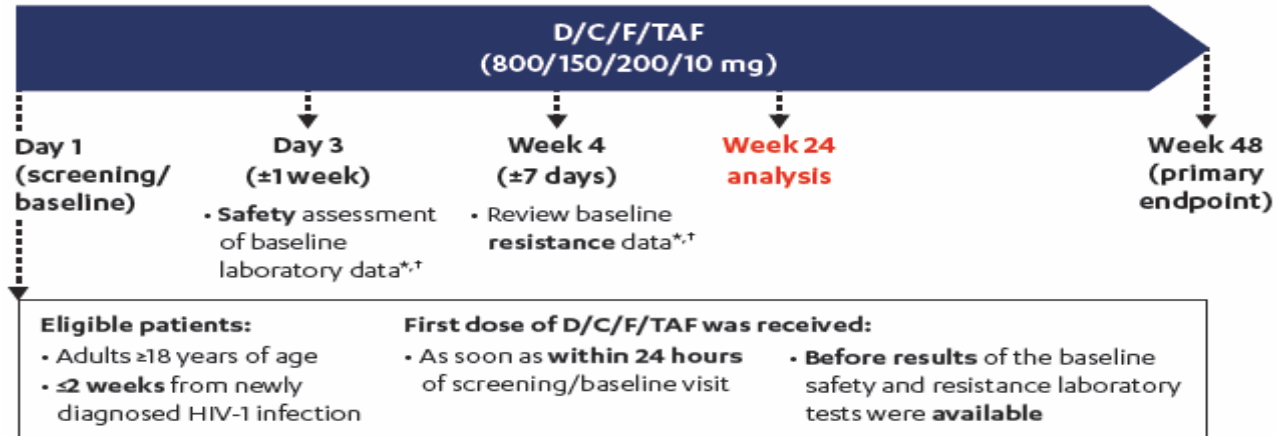
J Acquir Immune Defic Syndr • Volume 74, Number 1, January 1, 2017

LOI IDRES

Grometti et al,  
Antivir Ther, 2016

# DIAMOND: DRV/c/FTC/TAF modelo de Test-and-Treat con DRV/c/FTC/TAF (análisis interino)

EC Fase 3, un solo brazo, abierto: D/C/F/TAF como TAR de inicio rápido



## Documento de consenso del tratamiento antiretroviral en adultos infectados por el VIH (Version 2014)

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Si las evidencias disponibles demuestran mayor eficacia TAR inmediato y recomendaciones en sentido contrario no estan avaladas por evidencias...

**¿Tenemos que esperar a GODOT?**



# Suprimir la replicación del VIH es la mejor estrategia para prevenir su transmisión



- 1.110 parejas serodiscordantes homo/heterosexuales
- Análisis interino a los 2 años:  
Ningun caso de transmisión con **ARN-VIH <200 cop/ml**

# Suprimir VIH es la mejor estrategia para prevenir la transmisión sexual

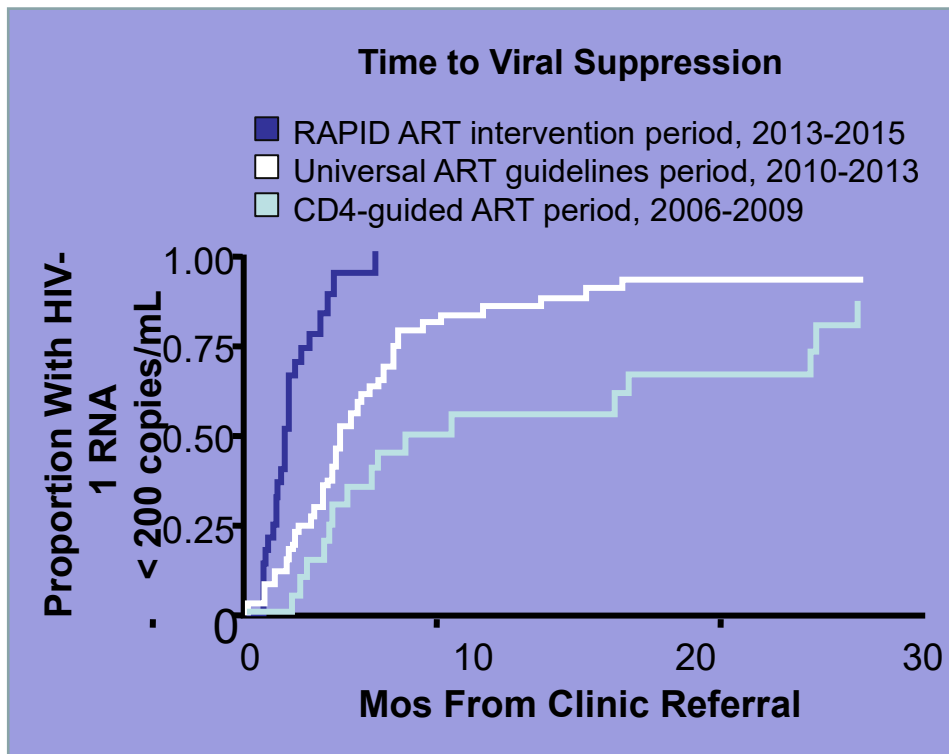
Study	Nº	Parejas 4w	Riesgo
<b>Ipergay</b>	400	10	HSH
<b>Partner PrEp</b>	2499	4	HTX
<b>IPREX</b>	4747	18*	HSH
<b>FEM-PrEp</b>	2120	1-11**	Mujeres

\*12 semanas

\*\* Ultima semana

# RAPID (Rapid ART Program Initiative for HIV Diagnoses): estudio Piloto en San Francisco

Inicio de TAR mismo día del diagnóstico (RAPID ART). Including access to labs and counseling. Including vulnerable populations (racial/ethnic minorities and homeless patients).



Time Diagnosis to first virologic suppression decreased 54% (from 134 days to 61 days)

Si el TAR inmediato contribuye a reducir la carga viral poblacional y adelanta la supresión de ARN-VIH...

**¿Tenemos que esperar a GODOT?**





# Recomendaciones de las Guías

## Guidelines<sup>1-4</sup>

## Recommendation

WHO<sup>1</sup>



- ART initiation within **7 days** for all people living with HIV following confirmed diagnosis and clinical assessment
- **ART initiation offered on the same day to people who are ready to start**

DHHS<sup>2</sup>



- ART for all individuals with HIV, regardless of CD4 T lymphocyte cell count
- ART initiation **as soon as possible** (may be deferred because of clinical and/or psychosocial factors)

IAS-USA<sup>3</sup>



- **ART initiation as soon as possible after diagnosis, including immediately after diagnosis**, unless patient is not ready to commit to starting therapy

EACS<sup>4</sup>



- ART irrespective of the CD4 count (lower the CD4 count = **greater urgency** to start ART **immediately**)
- **Accumulating evidence that ART initiation the day after establishing diagnosis is feasible and acceptable to HIV-positive persons**

ART, antiretroviral therapy.

1. WHO. Jul 2017. <http://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/>;

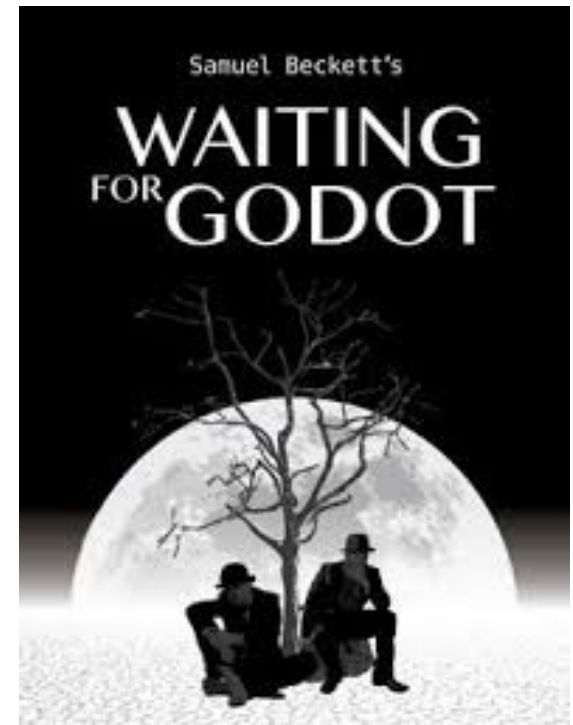
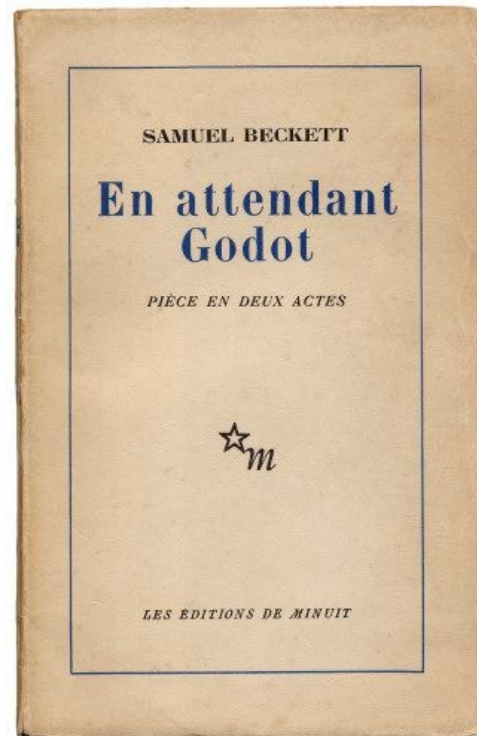
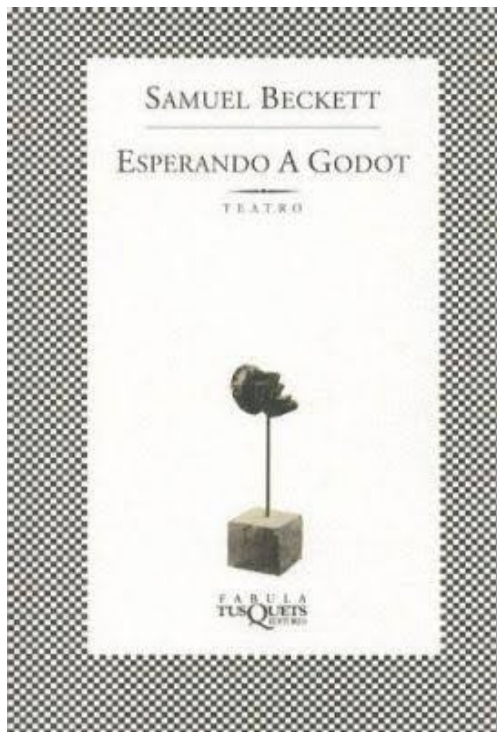
2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Oct 2018. <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>;

3. Saag MS, et al. JAMA 2018;320:379–396; 4. EACS. Oct 2018. [http://www.eacsociety.org/files/2018\\_guidelines-9.1-english.pdf](http://www.eacsociety.org/files/2018_guidelines-9.1-english.pdf).

# Documento de consenso del tratamiento antiretroviral en adultos infectados por el VIH (Versión Enero 2019)

- El TAR debe instaurarse **lo más rápidamente posible una vez confirmado el diagnóstico (A-III)**
- Se debe realizar siempre una **determinación de linfocitos CD4+ y CVP** previa al inicio del tratamiento, **aunque no es imprescindible esperar hasta disponer de los resultados**

# Recomendación



# Recomendaciones

**¡ No esperen a GODOT !**

Ni para decidir iniciar TAR

Ni como estrategia de vida