BARCELONA RESPIRATORY NETWORK
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Scientific workshops to foster collaborative research

RECERCA EN TB

Sala Geron 3, Planta -1. Edifici Montseny. Parc Sanitari Pere Virgili. → 18 Gener 2018

Xarxes internacionals d'assajos clínics: Centers for Disease Control and Prevention (CDC), Serum Staten Institut (SSI) i Unitat d'Invest. en TB de BCN (UITB).

Joan A. Caylà
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uitb

Unitat d'Investigació en Tuberculosi de Barcelona
Unidad de investigación en Tuberculosis de Barcelona
Tuberculosis Investigation Unit of Barcelona

/fuiTB
fundació uiTB
fundación uiTB
foundation uiTB

@TB_UITB http://www.uitb.cat

THE TB PROGRAMME IN 1986

- **Important under-reporting.**

From 1971 to 1981: average of 149 notified cases per year…

- **Possibilities of prevention and control**

COMPARACIO CASOS NOTIFICATS-EXITUS PER TUBERCULOSI A LA CIUTAT DE BARCELONA (1971-1980).

Any	Casos notificats	Exitus
1971	170	129
1972	139	107
1973	135	98
1974	137	88
1975	129	71
1976	135	71
1977	188	69
1978	149	34
1979	166	34
1980	187	29
1981	109	26

Font: Memòries del Servei d'Epidemiologia dels anys corresponents.

Ajuntament de Barcelona
Àrea de Sanitat, Salut Pública i Medi Ambient

Why a TB Program?

Programa de prevenció i control de la tuberculosi a la ciutat de Barcelona

Analisi dels casos declarats de tuberculosi a l´any 1986

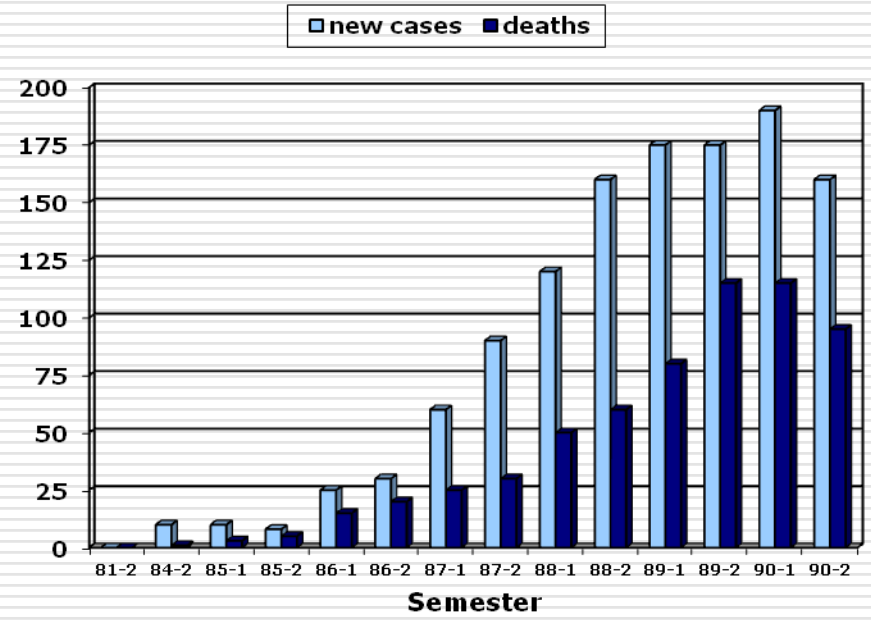
INSTITUT MUNICIPAL DE LA SALUT

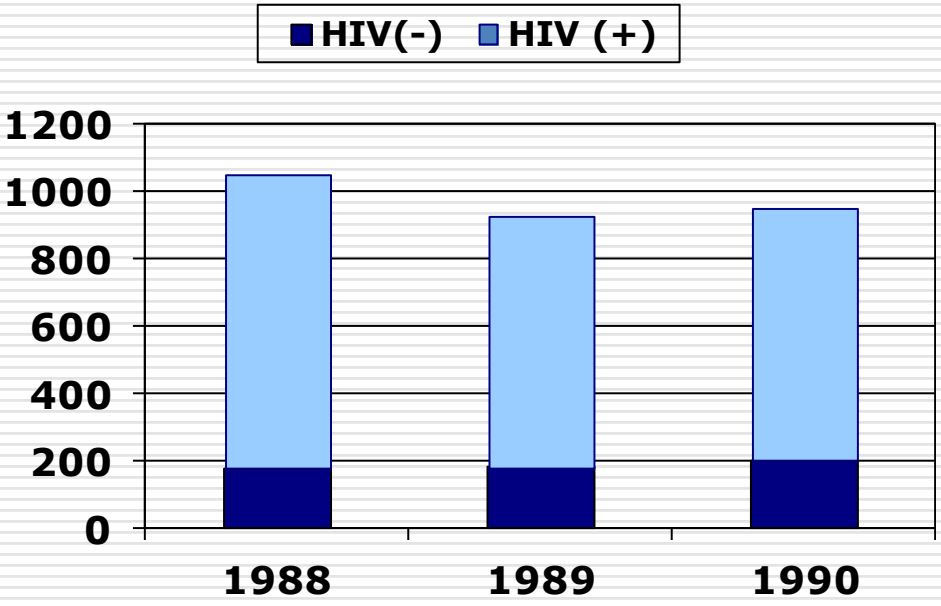
Servei d'Epidemiologia i Estadístiques Vitals

Epidemiological study about AIDS and TB in Barcelona, 1988-1990. (FIS 88/2128).

Investigators from: H Clínic, St Pau, Mar, Vall Hebrón, Disp.Tòrax, Dep. Justícia and ASPB. => 3 fellowships (physician, nurse, secretary)

AIDS and TB according to HIV, Barcelona (1988-1990)





IVDU

381

HIV(+)

206 (54,0%)

HIV (-)

175 (45,9%)

16 TB

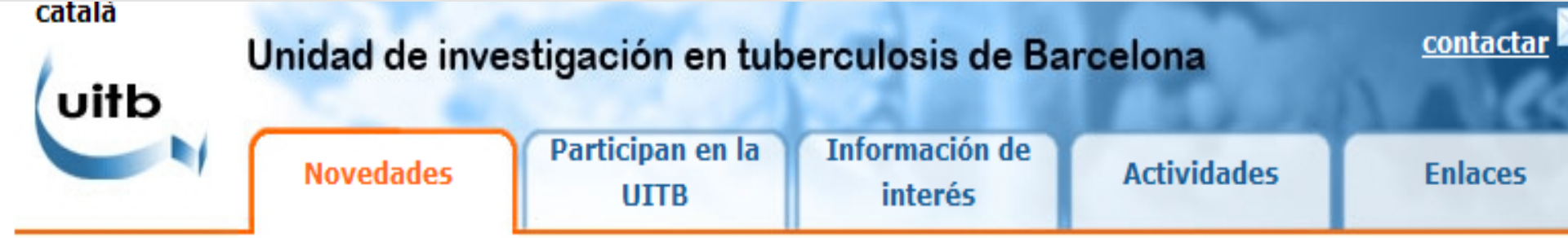
2 TB

TB incidence until 1994:

Coinfected people under LTBIT: 3.44/100 py.

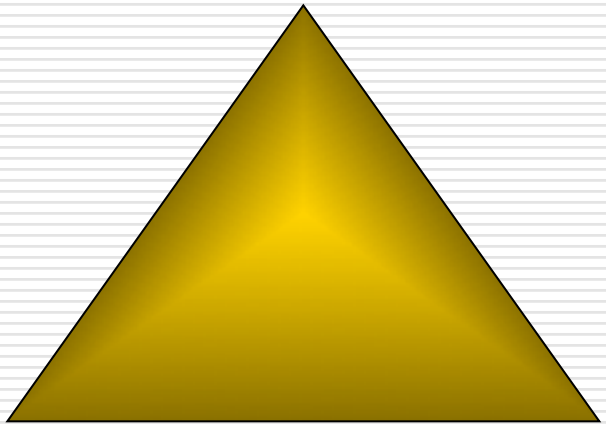
Coinfected people without LTBIT: 5.43/100 py.

Influence of HIV in the incidence of TB in a cohort of IVDU: effectiveness of anti-TB chemoprophylaxis. IJTLD 1998.



Unidad Temática del FIS (1995, material informático a 9 centros y a diversos servicios): Tuberculosis/AIDS/Immigration/Economic recession

Epidemiologists



Clinicians

Microbiologists

web: UITB.CAT

twitter: @TB_UITB

2016: /fuiTB fundació uiTB fundación uiTB foundation uiTB

World TB Day: March 15 2018

XXII TB International Congress. Nov 2018

INT J TUBERC LUNG DIS 9(3):276–281

Is the combination of pyrazinamide plus rifampicin safe for treating latent tuberculosis infection in persons not infected by the human immunodeficiency virus?

C. Tortajada,* J. Martínez-Lacasa,† F. Sánchez,*‡ A. Jiménez-Fuentes,§ M. L. De Souza,§ J. F. García,¶ J. A. Martínez,# J. A. Caylà*

2RZ should only be considered when other regimens are unsuitable and intensive monitoring of liver function is feasible.

JIP

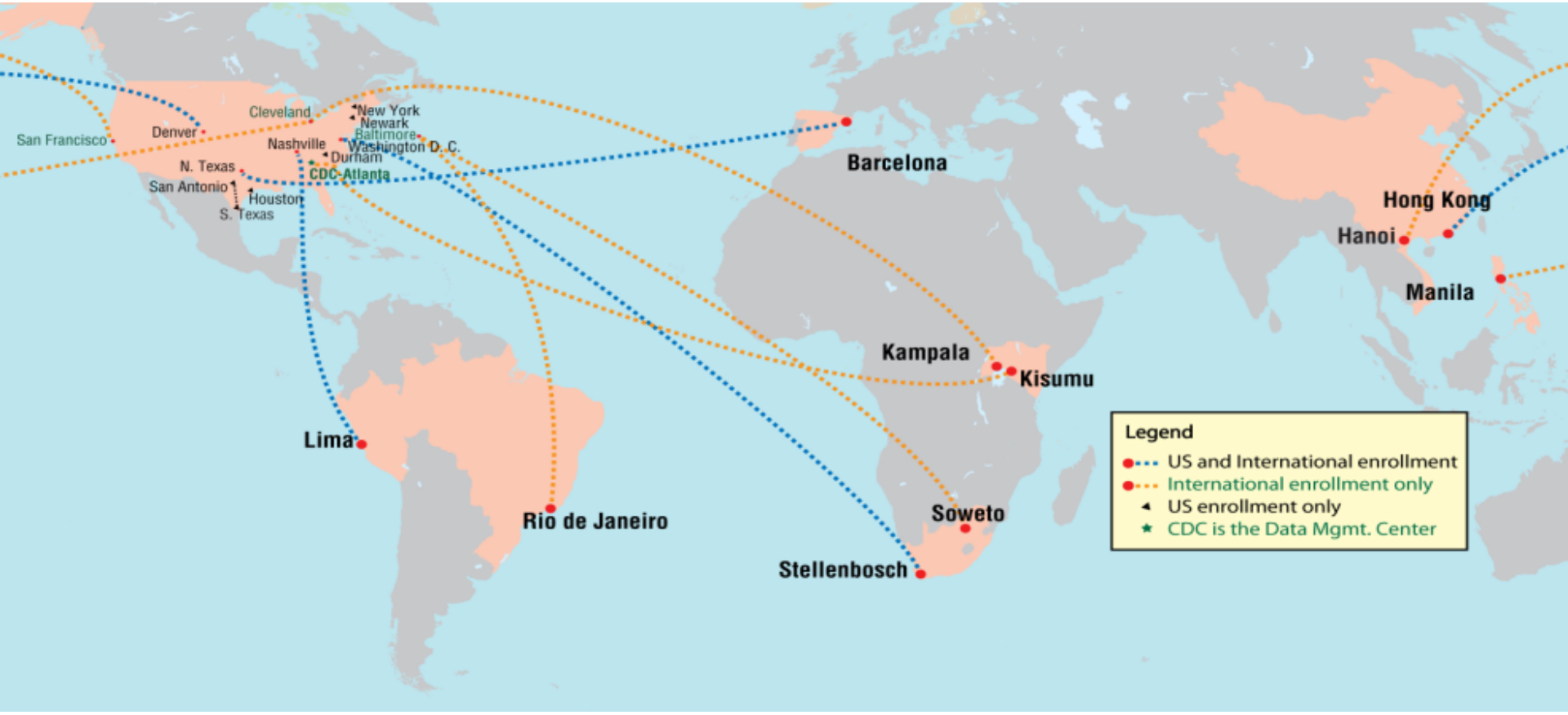
Treatment of latent *Mycobacterium tuberculosis* infection in intravenous drug users co-infected with HIV

Francesca Sánchez[1], Montse Balagué[2], Patricia García de Olalla[2], José L. López Colomés[1], Vicente Martín[3], Rafael Guerrero[4], Andrés Marco[4], Joan A. Caylà[2]*

2RZ should be considered an option to prevent TB in selected groups of patients infected with HIV, such as injection drug users on methadone treatment. J Infect Prevent 2010.

TBTC/CDC Sites and Partner Institutions 2003-2017

20 sites (10 from the USA, 10 international sites)



TBTC
TB Trials Consortium

3.630.630 € : 4 contratos, etc

uitb

What is the **Barcelona Tuberculosis Investigation Unit** (UITB)?

Unitat de Investigació en Tuberculosi de Barcelona

Clinical trials

The UITB, established in 1995, is focused on the scientific research and the dissemination of information related to tuberculosis (TB). Our main objective is the production of relevant scientific knowledge on the diagnosis, treatment, prevention and control of TB, TB-HIV and TB in immigrant population. These investigations are based on multicenter and multidisciplinary studies, and specially in clinical trials.

The UITB is one of the sites that participate in the Tuberculosis Trials Consortium (TBTC) of the CDC from USA.

CDC/TBTC Sites and Partner Institutions 2010-2020

Participant centers

- Agència de Salut Pública de Barcelona
- Hospital del Mar
- Hospital de Sant Pau
- Hospital de la Vall d'Hebron
- Hospital Mútua de Terrassa
- Hospital Clínic
- Unitat de Tuberculosi de Drassanes
- Hospital de Bellvitge

TBTC clinical trials

Some publications

- **TBTC Study 26.** Sterling TR, et al. Three months of rifapentine and isoniazid for latent tuberculosis infection. N Engl J Med 2011;365:2155-66.
- **TBTC Study 28.** Dorman se, et al. Substitution of Moxifloxazin for Isoniazid During Intensive Phase Treatment of Pulmonary Tuberculosis. Am J Resp Crit Care Med 2009, 180:773-780.
- **TBTC Study 29 and 29X.** Dorman SE, et al. Substitution of rifapentine for rifampin During intensive phase treatment of pulmonary tuberculosis study 29 of the tuberculosis trials consortium. J Infect Dis. 2012 Oct 1; 206(7):1030-1040.

Recent and future trials

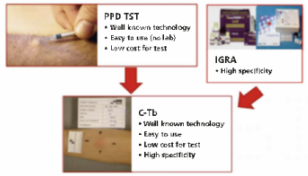
- **TBTC Study 33.** Assessment of adherence to treatment for latent tuberculosis infection with 12 doses of rifapentine and isoniazid once a week versus self-administered directly observed treatment in I-Adhere.
- **TBTC Study 31.** Rifapentine-containing treatment shortening regimens for pulmonary tuberculosis: A randomized, open-label, controlled phase 3 clinical trial.

Statens Serum Institut (SSI) clinical trial

The UITB also has participated with the SSI from Denmark in a phase III contact tracing trial comparing the diagnostic performance of C-TB to Quantiferon-TB Gold In Tube, in combination with a double blind randomized split body safety assessment of C-Tb versus 2 TU Tuberculine PPD RT23 SSI.

C-Tb improves present diagnostic methods

C-Tb combines the strenghts of existing diagnostic methods



What is the **Barcelona Tuberculosis Investigation Unit** (UITB)?

Unitat de Investigació en Tuberculosi de Barcelona

Observational Studies and Workshops

Since its establishment, professionals from UITB have participated in clinical trials but also in observational studies. The research is always based on multicenter and multidisciplinary studies.

Also, the UITB organizes national and international conferences and workshops about TB and emerging diseases.

The UITB centers, have participated in an observational study about **coinfection HIV-TB** in Europe and Argentina called Euro-TB, coordinated by Copenhagen HIV Programme, with the support of the European Union. Up to **47** HIV-positive patients were included in our hospitals.

Integrated in TBNet, the UITB has worked in the study of **MDR in Europe**, coordinated by the Research Center of Borstel, Germany, in these last five years.

Yearly, we organize the International Workshop about TB

Annually, the Emerging Diseases Workshop takes place in Barcelona conducted by the UITB

World TB Day 2015

Substitution of Moxifloxacin for Isoniazid during Intensive Phase Treatment of Pulmonary Tuberculosis

Susan E. Dorman[1], John L. Johnson[2], Stefan Goldberg[3], Grace Muzanye[4], Nesri Padayatchi[5], Lorna Bozeman[3], Charles M. Heilig[3], John Bernardo[6], Shurjeel Choudhri[7], Jacques H. Grosset[1], Elizabeth Guy[8], Priya Guyadeen[9], Maria Corazon Leus[10], Gina Maltas[1], Dick Menzies[11], Eric L. Nuermberger[1], Margarita Villarino[3], Andrew Vernon[3], Richard E. Chaisson[1], and the Tuberculosis Trials Consortium*

[1]Johns Hopkins University Center for TB Research, Baltimore, Maryland; [2]Department of Medicine, Division of Infectious Diseases, Case Western Reserve University and University Hospitals Case Medical Center, Cleveland, Ohio; [3]Centers for Disease Control and Prevention, Atlanta, Georgia; [4]Uganda-Case Western Reserve University Research Collaboration, Kampala, Uganda; [5]CAPRISA and Department of Community Health, University of KwaZulu Natal, KwaZulu Natal, South Africa; [6]Boston University School of Medicine, Boston, Massachusetts; [7]Bayer, Inc., West Haven, Connecticut; [8]Baylor College of Medicine, Houston, Texas; [9]Westat, Rockville, Maryland; [10]University of Medicine and Dentistry of New Jersey, Newark, New Jersey; and [11]McGill University, Montreal, Quebec, Canada

Rationale: Moxifloxacin has potent activity against *Mycobacterium tuberculosis in vitro* and in a mouse model of antituberculosis (TB) chemotherapy, but data regarding its activity in humans are limited.
Objectives: Our objective was to compare the antimicrobial activity and safety of moxifloxacin versus isoniazid during the first 8 weeks of combination therapy for pulmonary TB.
Methods: Adults with sputum smear–positive pulmonary TB were randomly assigned to receive either moxifloxacin 400 mg plus isoniazid placebo, or isoniazid 300 mg plus moxifloxacin placebo, administered 5 days/week for 8 weeks, in addition to rifampin, pyrazinamide, and ethambutol. All doses were directly observed. Sputum was collected for culture every 2 weeks. The primary outcome was negative sputum culture at completion of 8 weeks of treatment.
Measurements and Main Results: Of 433 participants enrolled, 328 were eligible for the primary efficacy analysis. Of these, 35 (11%) were HIV positive, 248 (76%) had cavitation on baseline chest radiograph, and 213 (65%) were enrolled at African sites. Negative

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

Moxifloxacin has potent activity against *Mycobacterium tuberculosis in vitro* and in a mouse model of combination antituberculosis chemotherapy.

What This Study Adds to the Field

This study demonstrates that, in patients with smear positive pulmonary tuberculosis, a regimen including moxifloxacin, rifampin and pyrazinamide given during the first 2 months of treatment was highly active, but not significantly more active than a regimen of isoniazid, rifampin, and pyrazinamide using a surrogate marker of Week-8 culture negativity.

Ensayos clínicos en TITL. Estudio 26 y 33 de los TBTC-CDC

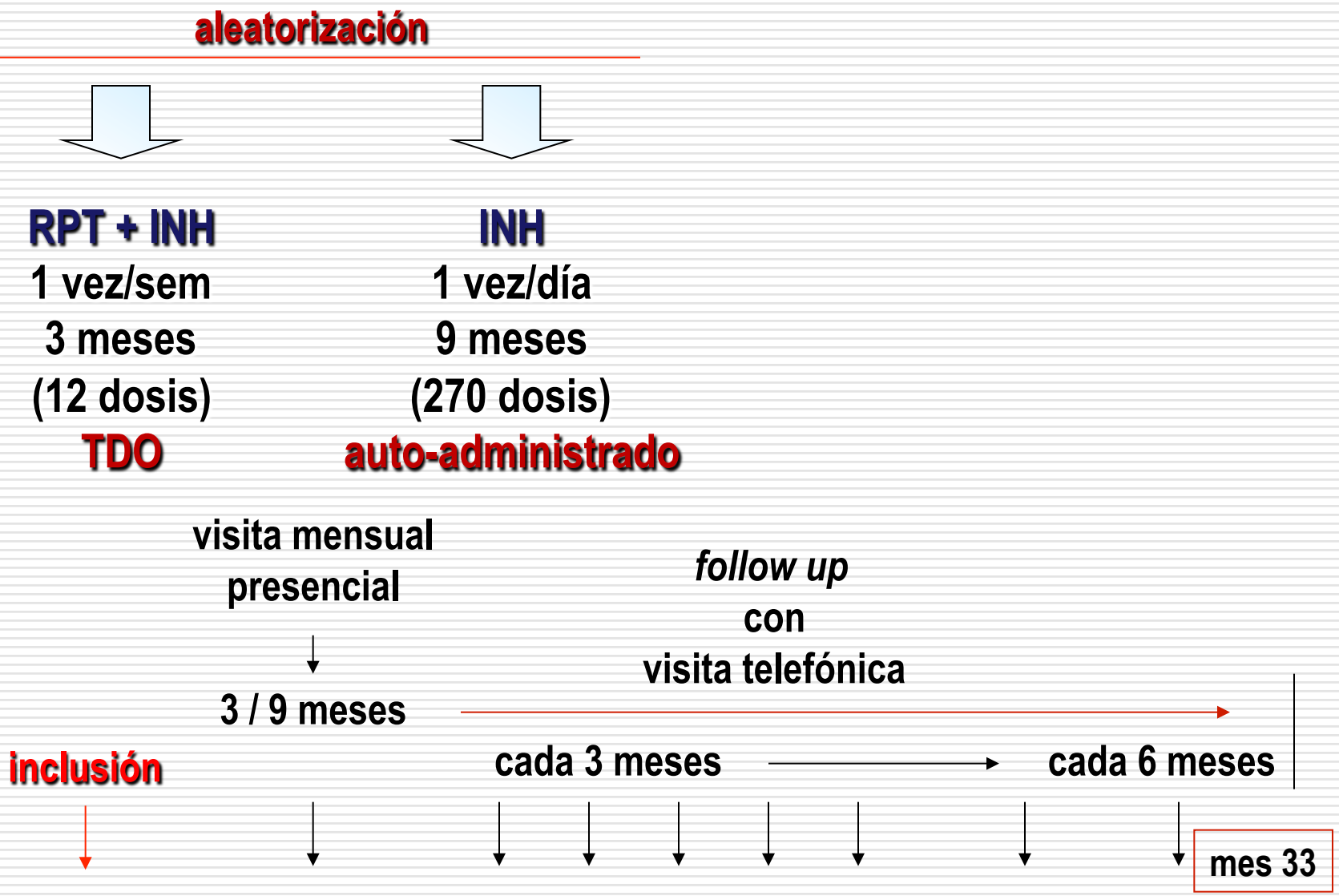
Study 26

Study 26: Evaluation of a Rifapentine (RFP) regimen for the treatment of latent TB infection

- **Standard regimen:** Isoniazid (H): once a day (9 months).
- **Experimental regimen:** H + RFP: once a week (3 months under DOT)

N Engl J Med. 2011: **Three months of rifapentine and isoniazid for LTBI.**

TBTC/UITB. estudio 26



Analysis Populations

Enrolled (ITT)	8,053
Eligible (MITT)	7,731
9H	3,745
3HP	3,986
Per protocol (PP)	5,858
9H	2,585
3HP	3,273

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 8, 2011 VOL. 365 NO. 23

Three Months of Rifapentine and Isoniazid for Latent Tuberculosis Infection

Timothy R. Sterling, M.D., M. Elsa Villarino, M.D., M.P.H., Andrey S. Borisov, M.D., M.P.H., Nong Shang, Ph.D., Fred Gordin, M.D., Erin Bliven-Sizemore, M.P.H., Judith Hackman, R.N., Carol Dukes Hamilton, M.D., Dick Menzies, M.D., Amy Kerrigan, R.N., M.S.N., Stephen E. Weis, D.O., Marc Weiner, M.D., Diane Wing, R.N., Marcus B. Conde, M.D., Lorna Bozeman, M.S., C. Robert Horsburgh, Jr., M.D., Richard E. Chaisson, M.D., for the TB Trials Consortium PREVENT TB Study Team*

- **The effectiveness of 3HP was not inferior to 9H: 3HP was at least as effective as 9H, and**
  - **the 3HP TB rate was approximately half that of 9H**
- **The 3HP completion rate was significantly higher than 9H (82% vs. 69%)**
- **3HP was safe relative to 9H: Lower rates of: Any adverse event andHepatotoxicity attributable to study drug**

Morbidity and Mortality Weekly Report (*MMWR*)

MMWR

Recommendations for Use of an Isoniazid-Rifapentine Regimen with Direct Observation to Treat Latent *Mycobacterium tuberculosis* Infection

Please note: *An erratum has been published for this article. To view the erratum, please click here.*

Weekly
December 9, 2011 / 60(48);1650-1653

Preventing tuberculosis (TB) by treating latent *Mycobacterium tuberculosis* infection (LTBI) is a cornerstone of the U.S. strategy for TB elimination (*1*,*2*). Three randomized controlled trials have shown that a new combination regimen of isoniazid (INH) and rifapentine (RPT) administered weekly for 12 weeks as directly observed therapy (DOT) is as effective for preventing TB as other regimens and is more likely to be completed than the U.S. standard regimen of 9 months of INH daily without DOT (*2*–*5*). This report provides CDC recommendations for using the INH-RPT regimen. The new regimen is recommended as an equal alternative to the 9-month INH regimen for otherwise healthy patients aged ≥12 years who have LTBI and factors that are predictive of TB developing (e.g., recent exposure to contagious TB). The new regimen also can be considered for other categories of patients when it offers practical advantages. Although the INH-RPT regimen was well tolerated in treatment trials, monitoring for adverse effects is recommended. Severe adverse effects should be reported to the Food and Drug Administration (FDA) and CDC.

Availability of rifapentine: FDC!
Monitoring for adverse events
Ability of TB programs to implement DOT
Study 33: Adherence of this treatment in DOT vs Self -administered (SAT) vs SAT+SMS reminders.

Study 33

Study 26: N Engl J Med. 2011: Three months of rifapentine and isoniazid for LTBI.

Study 33: An evaluation of adherence to LTBI treatment with 12 doses of once weekly RFP plus H given as: self-administered vs DOT vs SMS reminders.

Treatment of Latent TB Infection.

Tuberculosis Trials Consortium and Partners.
Atlanta, January 2011

Compliance with a 3 months RPT/H weekly regimen for LTBI treatment under self administration with SMS reminders vs DOT.

Joan A. Caylà
Site 31.
TB investigation Unit of Barcelona.
http://www.aspb.es/uitb

Tratamiento completado (MEMS). All & by sites

Country	MEMS						
	DOT	SAT			eSAT		
	Tx Comp	Tx Comp	Diff (95% CI)	p	Tx Comp	Diff (95% CI)	p
ALL	294/337 (87.2)	248/335 (74.0)	13.2 (7.3, 19.1)	0.28	249/326 (76.4)	10.9 (5.0, 16.7)	0.082
ESP	33/35 (94.3)	22/30 (73.3)	21.0 (3.4, 38.6)	0.75	28/33 (84.9)	9.4 (-5.0, 23.9)	0.23
HKG	14/15 (93.3)	11/14 (78.6)	14.8 (-10.2, 39.7)	0.49	16/16 (100.0)	-6.7 (-19.3, 6.0)	<0.001
USA	223/261 (85.4)	204/262 (77.9)	7.6 (1.0, 14.2)	0.014	191/249 (76.7)	8.7 (2.0, 15.5)	0.035
ZAF	24/26 (92.3)	11/29 (37.9)	54.4 (34.0, 74.8)	1.00	14/28 (50.0)	42.3 (21.1, 63.5)	0.99

Discontinuación por AEs:
3,6% DOT, 5,3%SAT, 4,3% eSAT

Annals of Internal Medicine ORIGINAL RESEARCH

Self-administered Versus Directly Observed Once-Weekly Isoniazid and Rifapentine Treatment of Latent Tuberculosis Infection

A Randomized Trial

Robert Belknap, MD; David Holland, MD, MHS; Pei-Jean Feng, MPH; Joan-Pau Millet, MD, MPH; Joan A. Caylà, MD, PhD; Neil A. Martinson, MBBCh, MPH; Alicia Wright, BS; Michael P. Chen, PhD; Ruth N. Moro, MD, MPH; Nigel A. Scott, MS; Bert Arevalo, BS, CCRP; Josè M. Miró, MD, PhD; Margarita E. Villarino, MD, MPH; Marc Weiner, MD;; and Andrey S. Borisov, MD, MPH; for the TB Trials Consortium iAdhere Study Team*

Background: Expanding latent tuberculosis treatment is important to decrease active disease globally. Once-weekly isoniazid and rifapentine for 12 doses is effective but limited by requiring direct observation.

Objective: To compare treatment completion and safety of once-weekly isoniazid and rifapentine by self-administration versus direct observation.

Design: An open-label, phase 4 randomized clinical trial designed as a noninferiority study with a 15% margin. Seventy-five percent or more of study patients were enrolled from the United States for a prespecified subgroup analysis. (ClinicalTrials.gov: NCT01582711)

Setting: Outpatient tuberculosis clinics in the United States, Spain, Hong Kong, and South Africa.

Participants: 1002 adults (aged ≥18 years) recommended for treatment of latent tuberculosis infection.

Intervention: Participants received once-weekly isoniazid and rifapentine by direct observation, self-administration with monthly monitoring, or self-administration with weekly text message reminders and monthly monitoring.

Measurements: The primary outcome was treatment completion, defined as 11 or more doses within 16 weeks and measured using clinical documentation and pill counts for direct observation, and self-reports, pill counts, and medication event-monitoring devices for self-administration. The main secondary outcome was adverse events.

Results: Median age was 36 years, 48% of participants were women, and 77% were enrolled at the U.S. sites. Treatment completion was 87.2% (95% CI, 83.1% to 90.5%) in the direct-observation group, 74.0% (CI, 68.9% to 78.6%) in the self-administration group, and 76.4% (CI, 71.3% to 80.8%) in the self-administration-with-reminders group. In the United States, treatment completion was 85.4% (CI, 80.4% to 89.4%), 77.9% (CI, 72.7% to 82.6%), and 76.7% (CI, 70.9% to 81.7%), respectively. Self-administered therapy without reminders was noninferior to direct observation in the United States; no other comparisons met noninferiority criteria. A few drug-related adverse events occurred and were similar across groups.

Limitation: Persons with latent tuberculosis infection enrolled in South Africa would not routinely be treated programmatically.

Conclusion: These results support using self-administered, once-weekly isoniazid and rifapentine to treat latent tuberculosis infection in the United States, and such treatment could be considered in similar settings when direct observation is not feasible.

Primary Funding Source: Centers for Disease Control and Prevention.

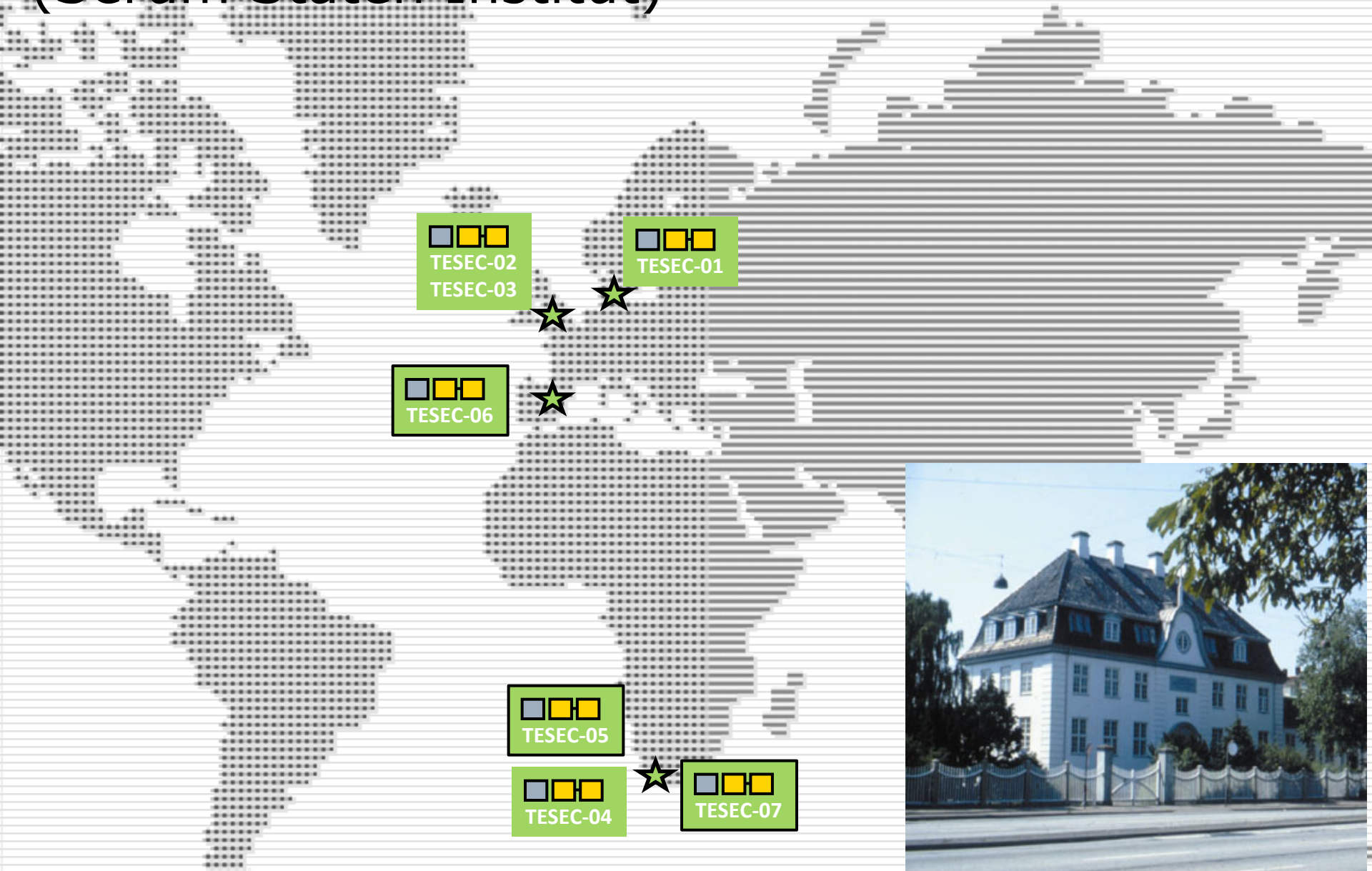
Ann Intern Med. doi:10.7326/M17-1150 Annals.org

For author affiliations, see end of text.

This article was published at Annals.org on 7 November 2017.

* For members of the TB Trials Consortium iAdhere Study Team, see Appendix 1 (available at Annals.org).

TESEC STUDIES: CLINICAL TRIALS WITH C-Tb (Serum Staten Institut)



Agència de Salut Pública
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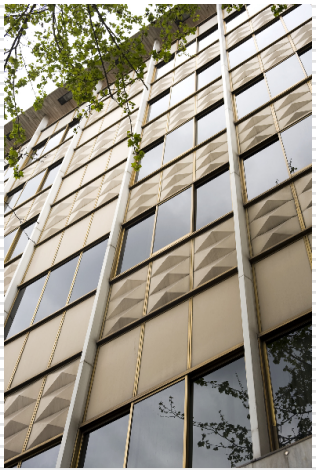
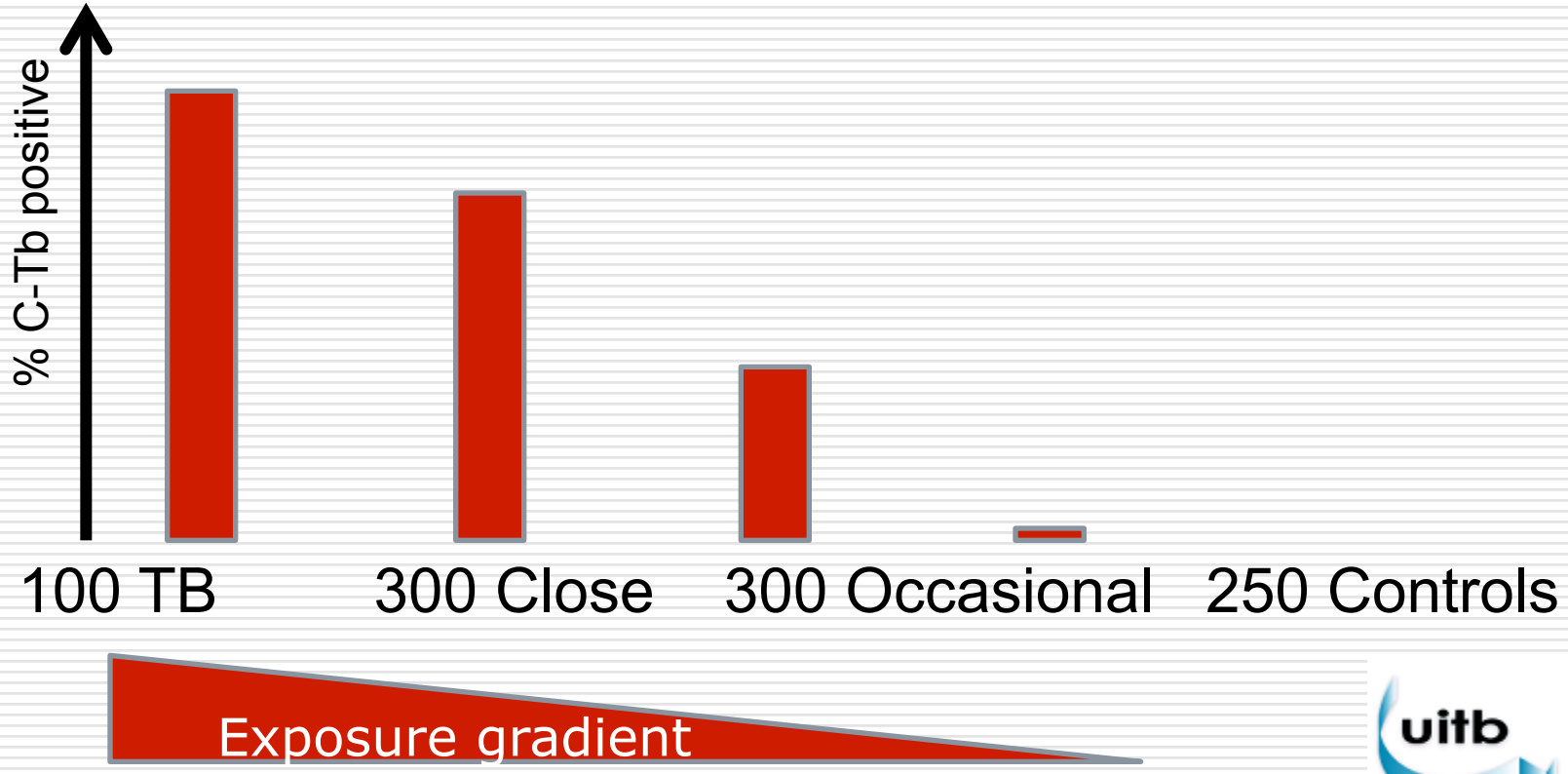
H. Mutua de Terrassa
H. Clínic
C. Drassanes
Unidades TB Galicia
H. de Cruces, Bilbao



TESEC-06 Objectives

- To demonstrate an increasing trend in C-Tb test positivity across four pre-specified risk level sub-groups
- To demonstrate superior specificity of C-Tb as compared to PPD
- To compare the diagnostic outcome of C-Tb, QFT and PPD



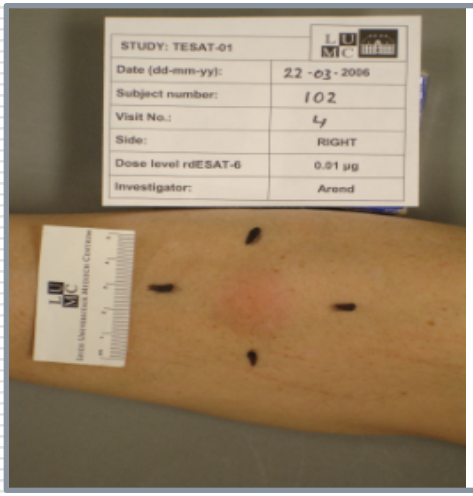
Basic idea of C-Tb

PPD TST

- Well known technology
- Easy to use (no lab)
- No blood draw
- Low cost per test

IGRA

- High specificity



C-Tb (rdESAT-6 and rCFP10)

- Well known technology
- Easy to use
- No blood draw
- Low cost per test
- High specificity

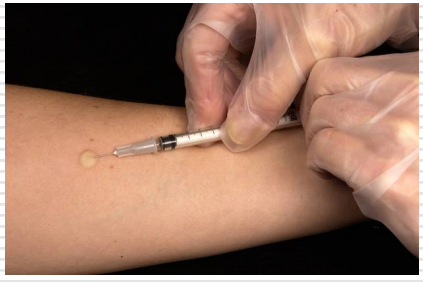
Administration of C-Tb and PPD

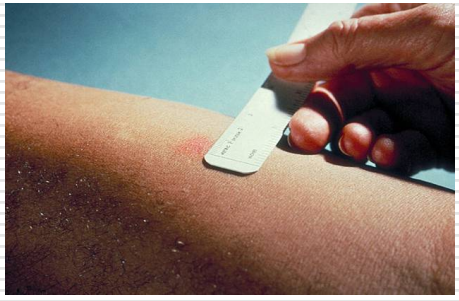
Concomitant administration of C-Tb and Tuberculin PPD RT23 SSI :

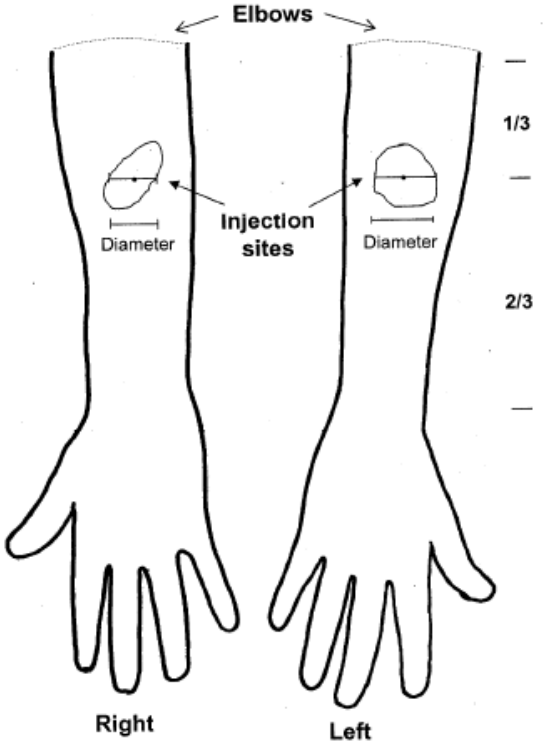
- 0.1 mL of the investigational diagnostic agent (C-Tb) is administered to the **right** or **left** forearm
- 0.1 mL of Tuberculin PPD RT23 SSI is administered to the opposite forearm

Administration of C-Tb alone

(50 participants)







Safety and efficacy of the C-Tb skin test to diagnose *Mycobacterium tuberculosis* infection, compared with an interferon γ release assay and the tuberculin skin test: a phase 3, double-blind, randomised, controlled trial

Morten Ruhwald, Henrik Aggerbeck, Rafael Vázquez Gallardo, Søren T Hoff, José I Villate, Bettine Borregaard, José A Martinez, Ingrid Kromann, Antón Penas, Luis L Anibarro, Maria Luiza de Souza-Galvão, Francisca Sánchez, Jose Ángel Rodrigo-Pendás, Antoni Noguera-Julian, Xavier Martínez-Lacasa, Maria Victoria Tuñez, Virginia Leiro Fernández, Joan P Millet, Antonio Moreno, Nazaret Cobos, José M Miró, Llanos Roldan, Angels Orcau, Peter Andersen, Joan A Caylá, the TESEC Working Group

Summary

Background Targeted screening and treatment of *Mycobacterium tuberculosis* infection substantially reduces the risk of developing active tuberculosis. C-Tb (Statens Serum Institute, Copenhagen, Denmark) is a novel specific skin test based on ESAT-6 and CFP10 antigens. We investigated the safety and diagnostic potential of C-Tb compared with established tests in the contact-tracing setting.

Methods Negative controls, close contacts, occasional contacts, and patients with active pulmonary tuberculosis were enrolled at 13 centres in Spain. We compared C-Tb with the QuantiFERON-TB Gold In-Tube ([QFT] Qiagen, Hilden, Germany) interferon γ release assay (IGRA) and the purified protein derivative (PPD) RT 23 tuberculin skin test ([TST] Statens Serum Institute). All participants older than 5 years were tested with QFT. Some participants in the negative control group received C-Tb without the TST to test for potential interactions between C-Tb and PPD RT 23. The rest were randomly assigned in blocks of ten and tested with both C-Tb and TST, with five in each block receiving injection of C-Tb in the right arm and the TST in the left arm and five vice versa. The primary and safety analyses were done in all participants randomly assigned to a group who received any test. This trial is registered with ClinicalTrials.gov, number NCT01631266, and with EudraCT, number 2011-005617-36.

Findings From July 24, 2012, to Oct 2, 2014, 979 participants were enrolled, of whom 263 were negative controls, 299 were occasional contacts, 316 were close contacts, and 101 were patients with tuberculosis. 970 (99%) participants completed the trial. Induration sizes were similar for C-Tb and TST, but TST positivity was affected by BCG vaccination status. We found a strong positive trend towards C-Tb test positivity with increasing risk of infection, from 3% in negative controls to 16% in occasional contacts, to 43% in close contacts. C-Tb and QFT results were concordant in 785 (94%) of 834 participants aged 5 years and older, and results did not differ significantly between exposure groups. The safety profile of C-Tb was similar to that for the TST.

Interpretation C-Tb delivered IGRA-like results in a field-friendly format. Being unaffected by BCG vaccination status, the C-Tb skin test might provide more accurate treatment guidance in settings where the TST is commonly used.

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Conclusions xarxes internacionals assajos clinics de TB:

- Permeten portar a terme assajos de qualitat amb recursos i durant anys
- Bona coordinació i col.laboració amb els professionals sanitaris locals: ajut pel Programa TB de BCN
- Quan estarà disponible 3HP en dosis fitxes medicamentoses?
- Quan el C-Tb?

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Gràcies !!!